# Centers for Medicare & Medicaid Services Special Study Pilot Testing of Electronic Prescribing Standards

#### **Final Report**

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## **Pilot Testing of Electronic Prescribing Standards**

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#### **Pilot Testing of Electronic Prescribing Standards**

#### Abstract

<u>Purpose</u>: To test multiple aspects of electronic prescribing within small, community-based practices.

<u>Scope</u>: The objectives of this study included measuring the impact of electronic prescribing on workflow, patient safety, and drug utilization as well as testing several initial standards. The initial standards tested include: 1) Medication History; 2) Fill Status Notification; 3) Prior Authorization; 4) Structured Sig; and 5) RxNorm.

<u>Methods</u>: This study focused on 25 e-prescribing primary care practices associated with University Hospitals Medical Practices in Cleveland, Ohio, as well as 22 non-e-prescribing practices located throughout Northeast Ohio. E-prescribing and control group practices were compared to establish differences in practice culture, workflow and efficiency and to determine critical issues in adoption of e-prescribing. Production tests of Medication History, Fill Status Notification, and Prior Authorization were conducted to determine the functionality of the standards and assess prescriber opinion. Laboratory tests were conducted of Structured Sig and RxNorm to assess the functionality of these initial standards.

Results: In testing RXFILL a significant lack of interoperability between NEWRX and RXFILL was found due to a lack of originating order number. Medication history is a mature and stable transaction. Patient identity matching still remains a major concern. Successful Prior Auth transactions took place during the study and the process was well-received by office staff. However, it would require substantial work on the part of health plans and RxHub to expand the electronic Prior Auth process to additional drugs and health plans. Non-productions tests of Structured Sig and RxNorm indicate that they are not ready for adoption in their current state. The impact of e-prescribing on patient safety appears positive. To accurately assess the impact on cost, formulary compliance and generic usage, additional analyses are required. Keywords: e-prescribing, community practices, standards, workflow, cost, patient safety

#### **Purpose**

This study was designed to test multiple aspects of electronic prescribing within small, community-based practices. Specifically, the main objectives of this project were:

- 1. To assess the impact of electronic prescribing on workflow in small, primary care practices.
- 2. To measure the impact of electronic prescribing on patient safety and drug utilization in those practices.
- 3. To test initial standards including Medication History, Fill Status Notification, Prior Authorization, Structured Sig, and RxNorm.

The project revolved around a group of small, community-based primary care practices owned by University Hospitals of Cleveland that have successfully implemented a foundation standard-compliant e-prescribing program. Since these practices were e-prescribing at the study inception, a concurrent control group of non-e-prescribing practices participated as well. The latter served as a comparison group for the projects workflow, safety and drug utilization analyses.

#### Scope

#### **Background**

This project was originally submitted to the Agency for Healthcare Research and Quality (AHRQ) in response to an RFA for an e-prescribing pilot test required by the Medicare Prescription Drug Improvement and Modernization Act (MMA). MMA requires that electronically transmitted prescriptions and certain other information for Part D covered drugs must comply with the final uniform standards. These standards must meet MMA's requirements, as well as be compatible with other standards, including standards adopted under the Health Insurance Portability and Accountability Act (HIPAA). MMA calls for the creation and testing of a set of electronic prescribing rules applicable to the electronic transmission of prescriptions and prescription-related information for drugs and patients covered under a Part D prescription benefit.

This project was not funded as a Cooperative Agreement with AHRQ under the original RFA. Instead, it was adopted and funded directly by the Centers for Medicare & Medicaid Services (CMS) as a Special Study Contract with Ohio KePRO, the Medicare Quality Improvement Organization (QIO) for Ohio. The alternate funding mechanism resulted in a 6-week delay to project kickoff (2/15/06 vs. 1/1/06).

#### **Context and Setting**

For this project, Ohio KePRO teamed with University Hospitals Medical Practices (UHMP), a subsidiary of University Hospitals of Cleveland. UHMP is comprised of more than 300 physicians in 90 primary and specialty care practices that are distributed among more than 40 communities throughout Northeast Ohio. UHMP practices service more than 1.3 million patient visits annually.

UHMP provided the study with a testing-ready group of small, community-based primary care practices that were already e-prescribing using the foundation standards. UHMP began a limited implementation of InstantDx's OnCallData<sup>TM</sup> e-prescribing application in mid-2004, and rapidly expanded this deployment throughout 2005. By February 2006, UHMP had a successful and stable (yet still growing) e-prescribing implementation.

Part of the success of this implementation may be due to several characteristics regarding OnCallData<sup>TM</sup>. First, OnCallData<sup>TM</sup> was integrated with the practice management system, Concept, in use by UHMP practices. Secondly, there were no up-front costs to the practices to implement OnCallData<sup>TM</sup>. There were no licensing costs and little to no hardware costs. Physicians who wanted to e-prescribe using a PDA, were required to purchase a device for about \$350. Additionally, OnCallData<sup>TM</sup> is delivered over the Internet via the Application Service Provider (ASP) model, eliminating the need for any UHMP personnel to maintain or manage the software. Similarly, training to use OnCallData<sup>TM</sup> was delivered remotely by InstantDx via WebEx at the request of the practice and/or user.

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<sup>&</sup>lt;sup>1</sup> RFA-HS-006-01, http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html

In addition, UHMP Administrators offered a \$500 discount on malpractice premiums to physicians who met required e-prescribing levels. The requirements were 250 e-prescriptions per month for a full-time primary care practitioner and 195 per month for a part-time primary care practitioner or a full-time pediatrician.

Ohio e-prescribing rules are also relevant to this study. In Ohio, the Ohio Board of Pharmacy must review and approve any e-prescribing application that is electronically transmitting prescriptions. These applications must either support authentication using biometrics or usernames and passwords. If the latter, less secure, method is used then daily audit logs must be printed and signed off on by each authorized prescriber using that e-prescribing application. The OnCallData<sup>TM</sup> e-prescribing application has been reviewed and approved by the Ohio Board. UHMP is using username and password based authentication with daily review of audit logs. Schedule II drugs must be printed and hand-Signed by the prescriber (no special paper requirement); Schedule III-V drugs may be sent from within OnCallData<sup>TM</sup> to pharmacies, but must be routed via OnCallData<sup>TM</sup>'s fax server to a fax machine at the pharmacy instead of via a true electronic transmission to the pharmacy system itself.

In Ohio, physicians and some nurse practitioners are authorized prescribers. Nurse practitioners have prescriptive authority only when they have taken additional classes and received certification for prescribing medications. Physician assistants currently do not have prescriptive authority in Ohio, but legislation was recently passed that will change their status when enacted.

Lastly, Ohio pharmacists are required to substitute generics for brand name drugs, when available; unless the prescriber expressly indicates on the prescription that substitution should not occur.

#### **Participants**

#### **Project Partners:**

Project participants include numerous technology, research, and data source partners. In addition to Ohio KePRO and University Hospitals of Cleveland the project partners include:

#### **Technology Partners**

- InstantDx (Gaithersburg, MD<sup>2</sup>): provide foundation standard-compliant e-prescribing tool to UHMP practices; develop new RXFILL and Prior Authorization transaction functionality and extend capabilities of existing prescription history transfer (RXHREQ and RXHRES) function; provide utilization statistics and other reporting
- RxHub, LLC (St. Paul, MN): support prescription history transfer (RXHRES) and provide related transaction metrics; support a production Prior Authorization test (with Anthem) and relevant monitoring and reporting

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<sup>&</sup>lt;sup>2</sup> http://www.OnCallData<sup>TM</sup>.com/

• SureScripts, LLC (Alexandria, VA): support production of RXFILL test with CVS, Walgreens and Rite Aid and provide relevant transaction metrics; provide data sample for RxNorm evaluation

#### Research Partners

- Medical Group Management Association's (MGMA) Center for Research: Based in Denver, the MGMA Center for Research is expert in practice-based research, especially in areas that concern healthcare information technology. David Gans, FACMPE, has helped develop and test the prescribing workflow assessment methods and tools described below. He has also contributed to overall study design for Stage 1 and assisted in analysis and interpretation of results.
- University of Minnesota, Division of Health Policy and Management: Based in Minneapolis, John Kralewski, PhD, is an expert on practice culture and its role in technology adoption. As the most senior researcher on the team, Dr. Kralewski was the primary architect of the study design for Stage 1. He has also provided existing tools which were developed and validated by him (the Medical Group Practice Culture Survey and the Medical Group Practice Organization Survey). He also assisted with the analysis and interpretation of results.

#### Health Plan Partners

- Anthem: Prior Authorization production test and provide cost and safety data for 12 percent of UHMP visit volume and uncertain percent of control practice visit volume
- Aetna: provide cost and safety data for 10 percent of UHMP visit volume and uncertain percent of control practice visit volume
- Medical Mutual of Ohio: provide cost and safety data for 18 percent of UHMP visit volume and uncertain percent of control practice visit volume
- QualChoice: provide cost and safety data for 13 percent of UHMP visit volume and uncertain percent of control practice visit volume

#### Other Secondary Data Sources

- Intelligent Health Repository, or IHR<sup>TM</sup> (Wolters Kluwer Health): formerly owned by NDCHealth; data pulled from claims adjudication transactions between pharmacies and payers; data available for over 70 percent of such transactions from retail pharmacies
- Concept<sup>TM</sup>: the practice management system at UHMP; ambulatory care encounter data for the UHMP study group practices

#### **Study Subjects:**

The study subjects consisted of two distinct groups of physicians in primary care practices: electronic prescribing (UHMP, e-prescribing, or study group) practices and non-electronic prescribing (non-UHMP, non-e-prescribing, or control group) practices. The e-prescribing practices where recruited from the 42 primary care UHMP practices already enrolled in UHMP's OnCallData<sup>TM</sup> e-prescribing program at the time of recruitment in the spring of 2006. (Additional eligibility requirements and recruitment methods are discussed below in the Methodology section.)

To achieve adequate sample size, we attempted to recruit 30 practices from each group. In May of 2006, there were more than 30 UHMP primary care practices that met the e-prescribing eligibility criterion. Ultimately, 25 of these practices agreed to participate and followed through with site visit commitments. (Described below in the Methodology section.)

The practice selection within UHMP can best be characterized as a convenience sample. However, since the majority of eligible practices were recruited, sampling bias at the practice level is unlikely.

The 25 e-prescribing study group practices, representing about 130 physicians, are categorized by size and primary care specialty in Tables 1 and 2. Fourteen of the practices (56 percent) are internal medicine<sup>3</sup> practices, six (24 percent) are pediatric practices, and the remaining 5 practices (20 percent) are family medicine practices.

**Table 1: Study Group Practices by Specialty** 

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Type of Practice	Number	Percent
Pediatrics	6	24%
Family Medicine	5	20%
Internal Medicine	14	56%
Total	25	100%

<sup>&</sup>lt;sup>3</sup> Denotes the specialty of the majority of the physicians in the practice; 3 of the 14 e-prescribing group internal medicine practices included at least one physician from another specialty, such as family medicine.

The practices were also categorized based on the number of physicians in each practice:

Small = 1 to 3 physicians, Medium = 4 to 8 physicians, and Large = 9 or more physicians.

Table 2: Study Group Practices by Specialty and Size

Type of Practice	Size of Practice	Number	Percent
Type of Fractice			
	Small	3	12%
Pediatrics	Medium	2	8%
	Large	1	4%
	Small	4	16%
Family Medicine	Medium	0	0%
	Large	1	4%
	Small	5	20%
Internal Medicine	Medium	8	32%
	Large	1	4%
Total		25	100%

The control group (non-e-prescribing) practices were recruited mostly (n=18) from a pool of practices that had an existing relationship with Ohio KePRO. The balance (n=4) were recruited via professional relationships with Dr. Barich. The only eligibility requirement for these practices was that they were primary care practices in Northeast Ohio that had not yet implemented electronic prescribing. Fifty practices were recruited; the majority via the KePRO channel, but only 22 agreed to participate and followed through with site visit commitments. Additional recruitment was attempted by placing a study advertisement in the local medical society journal, but there were no responses. The final control practice group size was thus 22, representing 77 physicians. Size and specialty of control group practices are shown in Tables 3 and 4. Of the 22 control group practices, eight (36 percent) are internal medicine, four (18 percent) pediatric and ten (45 percent) family medicine practices.

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<sup>&</sup>lt;sup>4</sup> The current 3 year CMS-KePRO contract is known as the 8th SOW, or Statement of Work (<a href="http://www.cms.hhs.gov/QualityImprovementOrgs/04\_sow.asp">http://www.cms.hhs.gov/QualityImprovementOrgs/04\_sow.asp</a>). As with similar contracts between CMS and QIOs in other states, it calls for KePRO to identify practices willing to install clinical information technology tools, such as e-prescribing and/or electronic medical records, and help those practices identify qualified technology and successfully install it. This project is called DOQ-IT (Doctor Office Quality - Information Technology) and the KePRO control practices were recruited from practices expressing an interest in the DOQ-IT project.

**Table 3: Control Group Practices by Specialty** 

Type of Practice	Number	Percent
Pediatrics	4	18%
Family Practice	10	45%
Internal Medicine	8	36%
Total	22	100%

**Table 4: Control Group Practices by Specialty and Size** 

	I	•	
Type of Practice	Size of Practice	Number	Percent
	Small	2	9%
Pediatrics	Medium	2	9%
	Large	0	0%
	Small	7	32%
Family Practice	Medium	2	9%
	Large	1	5%
	Small	5	23%
Internal Medicine	Medium	2	9%
	Large	1	5%
Total	-	22	100%

As with the UHMP study group, the control group practice selection was based on convenience. Given the nature of the true pool for control practice selection (all primary care practices in Northeast Ohio), convenience sampling is a larger source of potential bias with the control group than with the UHMP group.

#### **Incidence and Prevalence**

At the beginning of 2005, a year before this project began, there were 16 UHMP practices using OnCallData<sup>TM</sup>, generating 7,049 e-prescriptions in January 2005. One year later, in January 2006 there were 34 UHMP practices generating 30,330 e-prescriptions in January 2006, a 112 percent increase in practice participation over the previous January.

Three pharmacy chains participated in the pilot: CVS, Walgreens and Rite Aid. Approximately half of all electronic prescriptions generated by UHMP practices were routed to one of these pharmacy chains. This proportion was consistent throughout 2006. Of prescriptions routed to these three pharmacy chains, CVS had the largest share (50.9 percent), followed by Walgreens (31.4 percent) and Rite Aid (17.7 percent). See Tables 5 and 6 below for details.

Table 5: Number and Percent of Total eRx Routed to Individual Pharmacies in 2006

	C\	/S	Walgı	reens	Rite	Aid	Total eRx Routed
	Number	Percent	Number	Percent	Number	Percent	Number
January	8,230	51.5	4,892	30.6	2,846	17.8	15,968
February	8,244	51.6	4,976	31.1	2,760	17.3	15,980
March	10,152	50.8	6,276	31.4	3,542	17.7	19,970
April	9,084	51.9	5,414	31.0	2,993	17.1	17,491
May	10,758	50.8	6,721	31.8	3,689	17.4	21,168
June	10,173	51.6	6,086	30.9	3,462	17.6	19,721
July	9,255	50.8	5,664	31.1	3,299	18.1	18,218
August	10,342	50.9	6,186	30.5	3,785	18.6	20,313
September	9,902	50.0	6,415	32.4	3,476	17.6	19,793
October	11,019	49.8	7,199	32.5	3,915	17.7	22,133
November	10,910	50.7	6,802	31.6	3,821	17.7	21,533
December	10,605	50.5	6,622	31.5	3,765	17.9	20,992
TOTAL	118,674	50.9	73,253	31.4	41,353	17.7	233,280

Table 6: Total eRx Generated and Routed from January through November 2006

	Number	% of Total Routed	% of Total Generated
Total eRx Routed to CVS	118,674	50.9%	24.2%
Total eRx Routed to Walgreens	73,253	31.4%	15.0%
Total eRx Routed to Rite Aid	41,353	17.7%	8.4%
Total eRx Routed to All Three	233,280	100.0%	47.6%
Total eRx Generated	489,942		100.0%

Presumably, the overall pharmacy transaction volume, including mail order and e-prescriptions routed to all other pharmacies would be roughly equal to the total UHMP e-prescription volume (489,942 from January – December 2006) since it is rare for a prescription to be generated within OnCallData<sup>TM</sup> but then not routed electronically. Only Schedule II controlled substances are printed and taken to the pharmacy rather than routed electronically.

When a UHMP prescriber begins to write an electronic prescription for a patient within OnCallData<sup>TM</sup> their prescription benefit eligibility is automatically checked against RxHub's Master Patient Index (MPI). The MPI is a directory of members for all of the health plans and Pharmacy Benefit Managers (PBM) connected to RxHub. Roughly 2.9 million people reside in the Cleveland-Akron Consolidated Metropolitan Statistical Area (CMSA), 62.8 percent (1.8 million) of who are represented in RxHub's MPI.

More than a quarter million (299,857) prescription benefit eligibility checks were generated in OnCallData<sup>TM</sup> from January through December 2006. The majority of these checks (58.6 percent) came back positive meaning that the greater part of the prescriptions created within OnCallData<sup>TM</sup> were informed by eligibility-based formulary. See Table 7 for details concerning the number of eligibility checks and the proportion of positive responses.

Table 7: Prescription Benefit Eligibility Checks and Positive Responses in 2006

	Eligibility Checks	Positive Responses	Percent Positive
January	11,500	7,291	63.4
February	19,354	11,877	61.4
March	25,514	15,727	61.6
April	23,361	14,356	61.5
May	27,457	16,371	59.6
June	25,475	14,966	58.7
July	24,035	14,094	58.6
August	27,250	15,909	58.4
September	26,347	14,625	55.5
October	30,498	16,531	54.2
November	29,746	16,347	55.0
December	29,320	17,521	59.8
TOTAL	299,857	175,615	58.6

Similarly, when a prescriber begins to write an e-prescription for a patient within OnCallData<sup>TM</sup>, they have the ability to view a patient's paid prescription history (alternately referred to as "Medication History") by pressing a button on the website titled "PBM/Retail History." This capability has been in production at UHMP since before the project began, but it has changed over the course of the study period. At the beginning of the study, only insurance paid prescription drug data from RxHub was being transferred. Thus, if a patient paid cash for a drug, and a claim was not submitted to their insurer/PBM, the prescription would not appear in OnCallData<sup>TM</sup>'s Medication History display. However, beginning in October 2006, OnCallData<sup>TM</sup> began pulling dispensed prescription information via SureScripts and merged it with paid prescription claims data from RxHub.

While Medication History has been available during the entire study period, it has not been viewed very often. This is likely due to the fact that a majority of users were not aware that is was available. Table 8 presents the number of Medication History transfers and views by month. We began receiving this information from OnCallData<sup>TM</sup> in June 2006.

Table 8: Medication History Transferred and Viewed in 2006

	Medication History Transferred	Medication History Viewed	(%) Percent Viewed	Percent Change from Previous Month
June	12,324	117	0.95	
July	10,447	122	1.17	4.3
August	13,063	134	1.03	9.8
September	9,962	129	1.29	-3.7
October	12,464	488	3.92	278.3
November	11,807	579	4.90	18.6
December	13,295	184	1.38	-68.2
TOTAL	83,362	1,753	2.10	

Please note that the routing statistics discussed up to this point (the X12 270/271eligibility checks and the Medication History transfers RXHREQ/RXHRES) are for all 68 UHMP practices using OnCallData<sup>TM</sup>. We did not have transaction breakouts by practice, so we were not able to limit these statistics to our study group practices.

As of December 2006, the 68 UHMP

practices using OnCallData<sup>TM</sup> generated a total of 485,427 prescriptions. While the 25 study group practices represent just over a third of all UHMP practices, they account for more than 65 percent of the total number of electronic prescriptions generated. See Table 9 below. Given that study group practices account for 65 percent of the total e-prescription volume, we would assume that they would also represent 65 percent of the statistics presented above: routing, eligibility checks, and Medication History transfer.

**Table 9: Total eRx Generated by Study Group Practices** 

	Total eRx	Study Group eRX	Percent of Total
January		21,095	65.6
February	31,723	21,304	67.2
March	40,079	26,549	66.2
April	35,680	23,406	65.6
May	42,646	27,497	64.5
June	40,451	26,588	65.7
July	37,795	24,349	64.4
August	43,560	27,977	64.2
September	42,228	27,660	65.5
October	47,998	31,402	65.4
November	46,440	30,343	65.3
December	44,674	29,131	65.2
TOTAL	485,427	317,301	65.4

The volume of e-prescribing statistics generated by the study group practices has grown steadily over the course of 2006 from just over 21 thousand in January to more than 30 thousand in November. This occurred without any significant change in the number of UHMP physicians. The highest number of e-prescriptions per working day (Monday through Friday, excluding National holidays) was in December. Table 10 below shows the increase in the total study group e-prescriptions per working day by month.

Table 10: Total Study Group eRx by Work Day

	Total eRx (Study Group)	Working Days per Month	Total eRx/ Working Day	Percent Change from Previous Month	Percent Change YTD
January	21,095	21	1,005	N/A	N/A
February	21,304	20	1,065	6.0	6.0
March	26,549	23	1,154	8.4	14.9
April	23,406	20	1,170	1.4	16.5
May	27,497	22	1,250	6.8	24.4
June	26,588	22	1,209	-3.3	20.3
July	24,349	20	1,217	0.7	21.2
August	27,977	23	1,216	-0.1	21.1
September	27,660	20	1,383	13.7	37.7
October	31,402	22	1,427	3.2	42.1
November	30,343	21	1,445	1.2	43.8
December	29,131	20	1,457	0.8	45.0
TOTAL	317,301	21.2	1,250		

From initial discussions with study group practices, we quickly learned that many physicians in the study group practices were not actually using the OnCallData<sup>TM</sup> system themselves. Rather, a nurse or medical assistant was entering and sending the prescription on their behalf. Beginning in August, OnCallData<sup>TM</sup> was able to provide us with statistics of who was actually entering the prescription based on a unique username. From August through December, someone **other than the physician** entered 74 percent of all prescriptions generated in ONCALLDATA<sup>TM</sup> while physicians directly entered the remaining 26 percent. Pediatricians entered the highest proportion of prescriptions themselves (43 percent), followed by family medicine physicians at 38 percent. Interests directly entered only 18 percent of all e-prescriptions generated from August through December. See Table 11 for more detailed information.

Table 11: Study Group eRx Sent by the Physician and Surrogate by Specialty

	Study Gro	r				October		November		December		Total		
			August		September									
Specialty		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
Family														
Medicine	Other	3,060	63	2,729	63	3,201	62	3,155	60	2,793	60	14,938	62	
	<b>Physician</b>	1,790	37	1,574	37	1,948	38	2,119	40	1,853	40	9,284	38	
	Subtotal:	4,850		4,303		5,149		5,274		4,646		24,222		
Internal														
Medicine	Other	15,458	85	15,054	84	16,023	80	14,955	80	14,649	82	76,139	82	
	<b>Physician</b>	2,658	15	2,813	16	4,080	20	3,684	20	3,181	18	16,416	18	
	Subtotal:	18,116		17,867		20,103		18,639		17,830		92,555		
Pediatrics	Other	2,980	59	3,056	56	3,586	58	3,799	58	3,776	57	17,197	57	
	Physician	2,052	41	2,442	44	2,597	42	2,765	42	2,879	43	12,735	43	
	Subtotal:	5,032		5,498		6,183		6,564		6,655		29,932		
Total:	Other	21,498	77	20,839	75	22,810	73	21,909	72	21,218	73	108,274	74	
	Physician	6,500	23	6,829	25	8,625	27	8,568	28	7,913	27	38,435	26	
		27,998		27,668		31,435		30,477		29,131		146,709	-	

Note: the statistics regarding who entered the eRx vary slightly from the total eRx reported each month.

Beginning in August, OnCallData<sup>TM</sup> also began providing breakouts by prescriptions classified as "New" and "Renewal." However, only requests for renewals generated electronically by the pharmacy via the RXRENEW transaction are counted as "Renewals." For example, if a patient requests a renewal of their medication during an office visit and the prescriber enters it into OnCallData<sup>TM</sup> this will be classified as a "New" prescription as the request did not <u>originate from the pharmacy</u>. As a result, it is likely that the proportion of prescriptions classified as "Renewal" is vastly underestimated. From August through December, 91 percent of all e-prescriptions generated were classified as new prescriptions and 9 percent as renewals. When looking at the data by specialty, interests have the highest percentage of renewal prescriptions (12 percent) and pediatricians have the lowest (1 percent). This is not surprising given that the majority of prescriptions generated in a pediatrics practice are for acute conditions. See Table 12 below for additional details.

Table 12: New and Renewal Study Group eRx by Specialty

	August		September		October		November		December		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
New Rx	4,559	94	4,034	94	4,760	92	4,934	94	4,317	93	22,604	93
Refill	291	6	269	6	389	8	340	6	329	7	1,618	7
Subtotal:	4,850		4,303		5,149		5,274		4,646		24,222	
New Rx	15,914	88	15,917	89	17,876	89	16,423	88	15,627	88	81,757	88
Refill	2,202	12	1,950	11	2,227	11	2,216	12	2,203	12	10,798	12
Subtotal:	18,116		17,867		20,103		18,639		17,830		92,555	
New Rx	4,934	98	5,415	98	6,112	99	6,513	99	6,558	99	29,532	99
Refill	98	2	83	2	71	1	51	1	97	1	400	1
Subtotal:	5,032		5,498		6,183		6,564		6,655		29,932	
New Rx	25,407	91	25,366	92	28,748	91	27,870	91	26,502	91	133,893	91
Refill	2,591	9	2,302	8	2,687	9	2,607	9	2,629	9	12,816	9
	27,998		27,668		31,435		30,477		29,131		146,709	

Note: the statistics regarding script type vary slightly from the total eRx reported each month.

#### Methods

This project proceeded in four distinct (though partially overlapping) stages: Site Visits, Production Standards Testing, Laboratory Standards Testing, and Safety and Cost Impact Analyses. Our study design and methods can best be understood in the context of these project stages, as outlined below.

IRB oversight was provided by the University Hospitals of Cleveland Institutional Review Board. Two separate reviews were conducted, covering different stages of the project. The first review, covering site visits and standards testing, was completed in July (IRB # 06-06-26); the second, covering safety and cost impact analyses, was completed in November (IRB # 08-06-29).

#### **Stage 1: Site Visits**

The primary objectives of the site visits were to:

- measure the impact of e-prescribing on workflow including prescription-related phone call and fax volume
- characterize prescriber attitudes about e-prescribing and related features/functions, including those related to Fill Notification, Prescription History Transfer, and Formulary Compliance
- measure practice culture and organizational factors that could be related to e-prescribing adoption or use patterns, prescribing safety and/or cost (drug utilization) outcomes

Since there was no opportunity to perform baseline measurements prior to implementation of eprescribing software at the UHMP practices, our study design included a concurrent control group of non-UHMP, non-e-prescribing practices.

#### Study Subjects

See Participants section above (Study Subjects) for description of study practices.

In addition to being a UHMP primary care practice (internal medicine, family medicine, and pediatrics), eligibility for inclusion in the primary study group was based on there being at least one physician in the practice who generated at least 150 e-prescriptions in any month prior to recruitment. This criterion was an internally defined e-prescribing adoption criterion.

A single physician was recruited from within each UHMP and control practice for the Prescriber Interview and for the Session Log portion of the site visit, explained below. Physicians were eligible if they met the 150 e-prescriptions per month criterion. If multiple physicians met this criterion within a practice, the physician to be recruited was the Medical Director of the practice, however, if the Medical Director did not agree to participate a second physician was selected.

The payer mix for all UHMP practices, through April 2006 is represented in Table 13 below. The payer mix data suggests that Medicare is one of the largest single payers for UHMP

practices. Payer mix data are not available for the control group practices, though there is no reason to believe that it varies substantially from the UHMP practices given the regional proximity of the UHMP and control group practices.

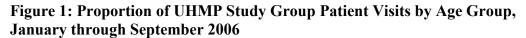
Table 13: Payer Mix for All UHMP Practices January through April 2006

	Percent of Total
Payer	Revenue
Aetna	6.12
Anthem	13.08
Medical Mutual	18.56
QualChoice	10.81
United Health Care	9.33
Other Commercial	12.48
Commercial Subtotal:	70.38
Medicare	17.90
Medicaid	9.51
Government Subtotal:	27.41
Unassigned	1.76
TOTAL	99.55

The patient age distribution for the UHMP study group practices, based on Concept<sup>TM</sup> practice management system<sup>5</sup> data is shown below in Tables 14 and Figures 1 and 2. The data are for 1/1/2006 through 9/30/2006.

Pilot Testing of Electronic Prescribing Standards

<sup>&</sup>lt;sup>5</sup> Actually, Concept<sup>TM</sup> is in use at only 24 of the 25 practices: One of the large-sized UHMP practices uses a different practice management system, and encounter data from this system was not available for this analysis



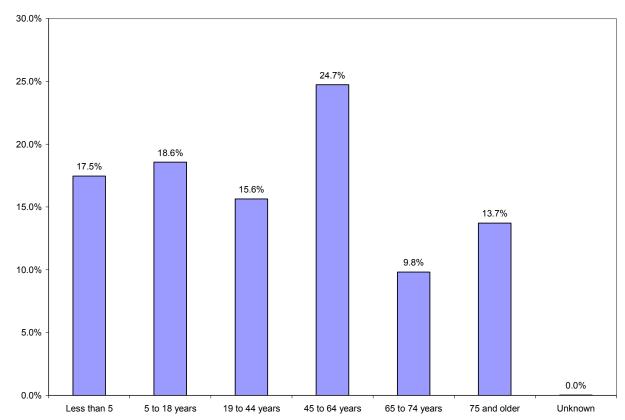


Figure 2: Proportion of UHMP Study Group Patient Visits by Specialty and Age Group, January through September 2006

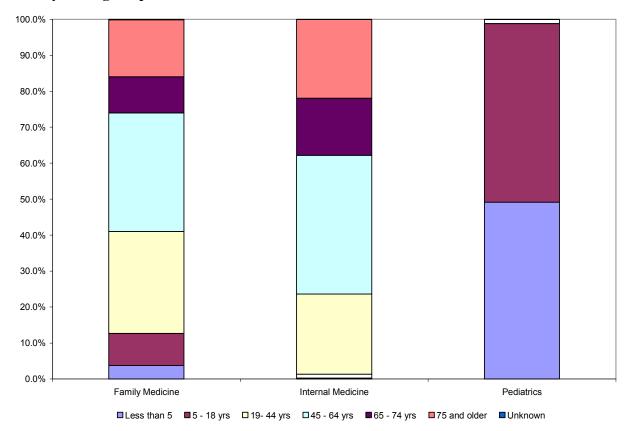


Table 14: Number of UHMP Patient Visits by Specialty and Age Group, January through September 2006

Specialty	Less than 5 yrs	5-18 yrs	19-44 yrs	45-64 yrs	65-74 yrs	75 & older	Unk	Total	% of Total
Family Medicine	1,627	3,845	12,233	14,215	4,345	6,838	59	43,162	10.3
<b>Internal Medicine</b>	586	2,521	51,135	88,405	36,405	50,289	47	229,388	55.0
Pediatrics	71,099	71,793	1,669				48	144,609	34.7
TOTAL	73,696	78,365	66,023	104,376	41,435	57,893	124	417,159	100.0

Please note that the largest family medicine practice (9 physicians) in the study does not appear in the encounter data because they have an electronic health record, and as such, do not use the Concept TM practice management system. The remaining four family medicine practices have 8 FTEs while the 14 internal medicine practices represented in the data above have approximately 90 FTEs and the six pediatric practices have roughly 36 FTEs. This may help explain the relatively low proportion of family medicine encounters.

These data show that the patients over the age of 65 (groups 5 and 6) represents about 24 percent of encounters at these 24 practices. Adults 65 and older account for 36 percent of UHMP encounters when pediatric practices are excluded.

#### Site Visit Methodology and Tools

The site visit methodology used in this project was developed almost entirely for this project.<sup>6</sup> Tools that were used during the site visits included:

- 1. Prescription Renewal Workflow Interview: A highly structured survey, completed by the office manager during the site visit, usually administered *verbally* by the site visitor as a structured interview. The focus of this tool was on how prescription renewals were handled by the practice.
- 2. Phone Call Tally Sheets: Designed for counting and recording call characteristics of all inbound and outbound prescription-related phone calls. These were to be completed by office staff handling these calls (unobserved by project team member) over a period of five consecutive weekdays, beginning as soon as possible after the site visit.
- 3. Fax Tally Sheets: Designed for counting inbound prescription-related request faxes from pharmacies. These were to be left at or near the fax machine(s) where these inbound faxes arrived, and were to be completed by whatever staff removed the fax from the fax machine. The forms simply called for a tick mark to be placed for each fax received. As with the Phone Call Tally Sheets, measurement was unobserved by site visit staff and was intended to occur over a period of five consecutive weekdays.
- 4. Selected Physician Interview: This tool was designed to gain information about the renewal workflow within the office and was conducted with the selected physician in each practice.
- 5. Session Log: Completed by the selected physician regarding a half day session seeing patients. This tool was design to gain information about the number of prescriptions written on average by the physicians. Physicians were asked to specify if the prescription was hand written or sent electronically and whether it was a new prescription or a renewal.
- 6. Prescriber Survey: A written survey distributed to all prescribers in the practice at the time of the site visit. This tool was designed to assess prescribing-related

.

<sup>&</sup>lt;sup>6</sup> While gracious assistance was provided by the RAND / UMDNJ and the Boston project teams, there was little, if any, of their work that was able to be leveraged for our project. Indeed, the only methods and tools *not* developed de novo were Dr. Kralewski's (U Minnesota) Medical Group Practice Culture and Organization surveys.

attitudes as well as capture subjective estimates of prescribing volume. There were 2 separate versions of this tool – one for the UHMP e-prescribing practices and one for the control practices (the former being considerably longer since it included questions about e-prescribing experience and attitudes that were irrelevant to the control practice prescribers)

- 7. Medical Group Practice Culture Survey (hereafter called "Culture Survey" for short): for all clinical staff in the practice. This tool was designed to assess the culture within the practice.
- 8. Medical Group Organization Survey (hereafter called "Organization Survey" for short): for the office manager to fill out. This tool was designed to gain information about the culture and structure of the practice.

Appendix A contains copies of the actual tools and the Site Visit Schedule, which references how the site visits were to be conducted, including a typical agenda.

All written survey tools that were distributed at the time of the site visits were accompanied by individual stamped return envelopes addressed to Ohio KePRO. The Organization Survey, Session Log, and Selected Physician Interview were usually completed and collected at the time of the site visit. All written surveys were anonymous with respect to individual respondent but contained a practice ID. Other than general follow-up appeals by site visitors for tool completion, there was no systematic effort to increase response rate (e.g., via repeated rounds of survey distribution or by reminder cards). This was primarily due to the lack of resources and time.

Both the Culture and the Organization Surveys were mature instruments at the time of project inception. However, the Culture survey had not previously been used or tested in small practices, and did not undergo any specific small practice pilot testing for this project.

The Organization Survey was believed by the project team to be too long especially in the context of all the other data collection and survey completion occurring around the site visits. Accordingly, a modified, shorter version of the Organization Survey was created for this project. In particular, those questions deemed least applicable to small practices were removed, with Dr. Kralewski's approval. However, at least one question important for the planned analysis was inadvertently removed from the Organization Survey. It was about the number of patients scheduled per clinic hour and was to serve as a measure of workload. No specific additional testing was done for the modified version.

There was also only limited testing of the newly developed tools (Renewal Workflow Interview, Prescriber Interview, Prescriber Survey, Phone Call and Fax Tally Sheets). These tools were iteratively developed, vetted and refined in rapidly successive cycles by Drs. Elson and Barich, Dave Gans (MGMA), John Kralewski (U Mn) and the KePRO clinical staff. The site visit methods and tools were pilot tested in early May at a single UHMP e-prescribing practice. Dave Gans was present for the test. The pilot test largely confirmed the applicability and acceptability of the methods and tools. Tool and method refinement continued through the summer. Because of limited pilot testing, feedback from the first wave of actual site visits in early September was reviewed immediately, but only minor adjustments were required. One significant problem with

the Prescriber Survey was that it did not cover surrogate-based e-prescribing. This turned out to be the predominant mode of e-prescribing at the UHMP practices but was not fully discovered until the site visits were well underway and it was too late to modify the tool.

A team of six site visitors (including Drs. Barich and Elson, and four KePRO staff members) conducted the site visits. The UHC Institutional Review Board (IRB) prohibited Dr. Barich from conducting site visits at UHMP practices due to his role as Chairman of Professional Affairs at UHMP. The site visitors were trained by Dr. Elson over three sessions conducted at Ohio KePRO, beginning in May. Dave Gans and Dr. Kralewski were also in attendance during the first training session. All site visitors became certified in Human Subjects Research by Case Western Reserve University as a requirement by the UHC IRB to obtain witnessed consent during the site visits. No attempt was made to evaluate inter-observer variability between the site visitors. While this was largely due to time and resource constraints, the site visits primarily involved the application and distribution of structured data collection tools rather than site visitor observation.

The site visits were conducted mostly in August and September, with a few visits in October 2006. The majority of UHMP site visits were conducted in August while the majority of control practice site visits were conducted in September. Because of planned roll outs of Rx Fill / NoFill in October, a deadline of September 30<sup>th</sup> was set for completion of the UHMP site visits. There was only a single site visit conducted after September 30<sup>th</sup>. (Figure 3 below) Because of seasonal variation in prescribing and/or prescribing-related phone call volume, this timing difference may be important.

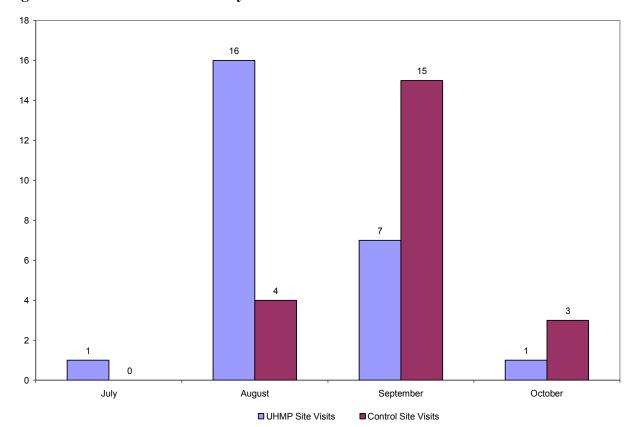


Figure 3: Number of Site Visits by Month

Besides the tool limitations noted above there were a couple of additional "regrets" that emerged regarding site visit methods:

- The Prescription Renewal Workflow tool focused almost exclusively on renewal requests that generated outside of the practice. In hindsight, it would have been valuable to include questions regarding the workflow around new prescriptions and renewal requests that occurred during a patient visit. This is especially important in light of the fact that the majority of eRx generated at UHMP practices are entered by someone other than the physician. It would have been helpful to get quantitative or qualitative data regarding the workflow involved when the eRx are entered into OnCallData<sup>TM</sup> TM by a surrogate.
- Site visitors were not asked to supply a loosely structured, free-text site visit narrative description of the visit. In retrospect, these narratives and a semi-structured guide on how to construct them should have been required. Such narratives often contain richer information than can be gleaned from structured data collection forms and can in turn, provide useful insights into practice culture and prescribing-related workflow. Examples of narrative that were recorded after site visits are included in Appendix B.

#### **E-Prescription Adoption Analysis**

Several statistical techniques were used to analyze the adoption of e-prescription in this study group. First, we conducted an overall analysis of the medical groups included in the study using descriptive statistics. Since the study design included a matching process, some of the practice

characteristics such as urban location did not vary. Consequently, the descriptive analysis included the 16 organizational factors and the nine culture scores that were not controlled by the matching process in the 45 practices.

The specific variables included in the analysis are below.

- I) Practice organizational characteristics
  - a) Ownership:
    - 1) hospital,
    - 2) another medical group,
    - 3) the practice physician
  - b) Tax classification:
    - 1) for profit,
    - 2) not-for-profit
  - c) Computer capabilities: Proportion of physicians who have
    - 1) computer terminals at patient care sites,
    - 2) computer-based patient data at patient care site,
    - 3) computer-based drug data at patient care site,
    - 4) have e-mail capacity at patient care site
  - d) Practice size: Number of FTE physicians
  - e) Practice specialty:
    - 1) interest,
    - 2) pediatrics,
    - 3) family practice
  - f) Number of support staff per physician
    - 1) Total RN, LPN and MA support staff per physician
    - 2) Have nurse practitioner or Physician Assistant (PA) (yes / no)
  - g) Have benchmarking programs (yes / no)
  - h) Conduct patient satisfaction surveys (yes / no)
  - i) Have drug sales representatives policies (yes / no)
  - j) Monitor patient use of services:
    - 1) monitor high cost patients,
    - 2) monitor patients with chronic illness
  - k) Conduct physician profiling (yes / no)
  - 1) Degree of centralization of decision making:
    - Response on a 1 to 5 scale regarding the degree to which the medical director and administrator make all of the important administrative decisions (5 = to a great extent)
- II) Practice Culture (all a 1 to 4 score with 4 =to a great extent)
  - a) Collegiality
  - b) Information emphasis
  - c) Quality emphasis
  - d) Management style
  - e) Cohesiveness
  - f) Organizational trust
  - g) Adaptive

- h) Autonomy
- i) Business orientation
- III) Physician characteristics
  - a) Age: Years
  - b) Gender: 1 = Female
  - c) Specialty:
    - 1 = interests.
    - 2 = pediatricians,
    - 3 = family practice,
- IV) Use of e-prescriptions
  - a) Adopted e-prescription technology at practice level: Y/N
  - b) Use of e-prescriptions at practice level: percent of total prescriptions<sup>7</sup> from the practices that were sent electronically during September 2006
  - c) Use of e-prescription at physician level: percent of total prescriptions sent by each physician that were sent electronically during September 2006

#### Workflow Differences Analysis

Analysis of the Prescription Renewal Workflow Interview tool was very straight forward. Descriptive statistics were calculated for all metrics, and then compared between the UHMP and control groups. T-tests were conducted to test the significance of differences between means of the metrics and Levene's Test was conducted to identify if the mean value was significant at the 95 percent Confidence Interval.

#### Phone Call and Fax Tally Sheet Analysis

After reviewing all Phone Tally Sheets completed and returned by the study groups, it was determined that the best representation of call volume would be the second day of data, typically Tuesday. This was based on the assumption that Monday call volume could be higher than normal and it would give the practice a day to develop a workflow for completing the Tally Sheets. The average number of phone calls for each practice was calculated and adjusted for the number of FTE physicians within the practice. The mean of e-prescribing practices was compared to the mean for all non-e-prescribing practices. The analysis was repeated to include total call volume from all days recorded by the practice. Subsequent analyses examined the overall volume and characteristics of incoming and outgoing calls separately. T-tests were conducted to test the significance of differences between means.

<sup>&</sup>lt;sup>7</sup> Total prescriptions were estimated by multiplying the number of patient visits that occurred in September 2006 by an estimate of the average number of drugs ordered during a patient visit. For our study, this drug multiplier number was 2.0 for internal medicine physicians, 1.3 for family medicine physicians and 0.6 for pediatricians. According to the National Ambulatory Medical Care Survey: 2004 Summary

<sup>(</sup>http://www.cdc.gov/nchs/fastats/drugs.htm), an average of 1.7 drugs were ordered or provided per visit. However, it is well known that pediatricians typically prescribe fewer drugs as up to half of their patient visits are for well-child care. Similarly, a study published in the Journal of the American Medical Informatics Association<sup>7</sup> found that general internal medicine physicians prescribed an average of  $2.73 \pm 3.0$  during each patient session. We adjusted these published multipliers for our analysis after an initial review of the encounter data and total number of *electronic* prescriptions generated by each provider.

Information about prescription-related faxes was also gathered. The fax tally sheet was designed to count inbound prescription-related faxes from pharmacies. These forms were much simpler than the phone call tally sheet and simply called for a tick mark to be placed for each fax received. As with the Phone Call Tally Sheets, measurement was unobserved by site visit staff and was intended to occur over a period of five consecutive weekdays. The average number of faxes for each practice was calculated and adjusted for the number of FTE physicians within the practice.

# **Stage 2: Production Testing of Initial Standards** (RXFILL, Prior Authorization, Medication History)

Two new initial standards-related features (RXFILL and Prior Authorization) were implemented into production via OnCallData<sup>TM</sup> at UHMP specifically for this project. A third (Medication History transfer) was already in production at project inception, and underwent production enhancements during the project that were neither directed by nor undertaken for this project. Nonetheless, these changes, coupled with a training intervention, provided an opportunity for testing in a production environment. Each of these three initial standards production tests are described separately below.

#### Prescription Fill Status Notification (RXFILL)

According to the original proposal, nine measures were outlined related to RXFILL:

- 1. Are the right data being sent? Are the data usable and accurate?
- 2. Are the data well-understood at all points? How long does the transaction take?
- 3. How does the transaction interoperate with other initial and with foundation standards?
- 4. How do physicians / nurses / pharmacists feel about Fill Status Notification?
- 5. How do patients feel about Fill Status Notification? About consent?
- 6. Would either physicians or pharmacists pay for this transaction, if asked to? If so, how much? If not, who should, if anyone?
- 7. Does e-prescribing with fill notification impact fill status?
- 8. When should a no-fill message be sent to the prescribing physician? After two days? Two weeks? At regular intervals until return-to-stock occurs?
- 9. What impact do fill notifications have on physician / nurse / pharmacist workflow?

While we were able to conduct a production test of the RXFILL transaction, we were unable to fully address some of these nine measures. Measures five and six could not be addressed at all. Moreover, while we intended (and, ultimately, thought we had successfully implement) a production test of NoFill alerting to prescribers, this testing was: a) not based on actual NoFill transactions (described in greater detail below), and; b) never actually occurred to a testable extent (explained further in Results section).

The production test itself would not have happened at all were it not for considerable persistence on our part followed by creativity and hard work on the part of SureScripts and InstantDx. The main obstacle to a production RXFILL / NoFill messaging test was that no retail pharmacy was

willing to participate directly in RXFILL / NoFill engineering. Since retail pharmacy was the intended originator of these messages, this was problematic.

A partial solution presented itself in the form of SureScripts' dispensed prescription repository, which went into production in late July of 2006. Since retail pharmacies were beginning to send dispensed prescription data to SureScripts' repository within 24 hours of a dispensing event, it was possible for SureScripts to use the receipt of that data to trigger an RXFILL notification transaction to OnCallData<sup>TM</sup>.

For the purpose of the pilot test, only prescriptions sent from OnCallData<sup>TM</sup> via a NEWRX transaction to a CVS, Walgreens or Rite Aid pharmacy would trigger an RXFILL message from SureScripts back to OnCallData<sup>TM</sup>. These three retail chains were the only Northeast Ohio pharmacies participating in SureScripts' prescription repository at the time of the project. Moreover, the production test was limited to nine of the 25 UHMP study group practices. These nine practices where chosen based on their specialty, e-prescription volume, and the utilization patterns of the prescribers (direct- vs. surrogate-based use of OnCallData<sup>TM</sup>). Three practices from each primary care specialty type (family medicine, internal medicine, and pediatrics) were chosen, with a mix of direct- and surrogate-based utilization patterns within each specialty grouping. This mix was intentionally chosen in order to test NoFill alerting under a range of specialty and workflow situations.

In order to restrict RXFILL transactions to those nine practices, SureScripts was provided with a list of DEA numbers for all of the prescribers in those practices (n = 34). RXFILL transactions to OnCallData<sup>TM</sup> would only be triggered upon the transfer to SureScripts of dispensed prescription data if the ordering prescriber DEA number matched the DEA number of one of our RXFILL study group physicians. More specifically, the "dispensed" data transferred from the pharmacies to SureScripts had to include a "picked-up" flag, rather than a flag indicating that the drug was simply dispensed.

Based on our professional judgment coupled with informal feedback from some of the nine study group practices and a formal discussion with UHMP risk management counsel, we did not believe that prescribers (or their surrogates) wanted to be actively alerted to every Fill event. Accordingly, OnCallData<sup>TM</sup> did not alert users to incoming RXFILL transactions. Instead, when an incoming RXFILL message was successfully matched to an original earlier outbound prescription (see matching discussion next paragraph), the filled status of the prescription was appended to the history of that prescription, and was retrievable upon lookup by users.

Linking an RXFILL message received from SureScripts to the original prescription created earlier within OnCallData<sup>TM</sup> required that somewhat elaborate matching logic be applied by OnCallData<sup>TM</sup>. This was necessitated by the fact the original (internally-generated) OnCallData<sup>TM</sup> outbound prescription order number was not available on the inbound RXFILL message. If this order number were tracked and communicated throughout the NEWRX to SureScripts Repository to RXFILL routing cycle, it would be simple to accurately close the loop by matching the RXFILL message with the original prescription order. However, this order number is not a required data element in NEWRX and is thus not reliably sent to pharmacy in the first place, although it may be included in NEWRX transactions sent from OnCallData<sup>TM</sup>.

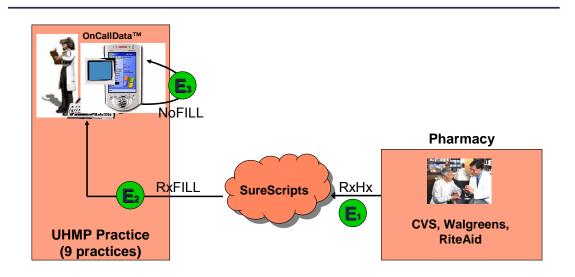
The matching logic used by OnCallData<sup>TM</sup> to link a RXFILL message with the original prescription includes a combination of the NDC code, the prescriber name, the prescription date, and the dispensing pharmacy.

While the SureScripts' repository-mediated solution described above was able to create true RXFILL transactions, it was unable to create true NoFill transactions, and no such transactions were built or tested as part of this project. Instead, OnCallData<sup>TM</sup> was able to use application logic to internally generate *presumed* NoFill alerts to prescribers. A NoFill event was **assumed** for any NEWRX prescription routed to a CVS, Walgreens or Rite Aid pharmacy for which a corresponding RXFILL notification **had not been received** by OnCallData<sup>TM</sup> within 10 days of the original NEWRX message. (Figure 4 visually shows the RXFILL / NoFill process.)

#### Figure 4: RXFILL / NoFill Data Transfers

Initial Standard: RXFILL / NoFILL (SCRIPT 8.1)

- Pharmacy transfers prescription history to SureScripts repository after drug is *picked up* (E1) in the case of CVS and Walgreens or, in the case of Rite Aid, after it has been *dispensed* (see Results text for further discussion)
- SureScripts sends OnCallData<sup>TM</sup> RXFILL message (E2)
- OnCallData<sup>TM</sup> presumes NoFill and alerts user if:
  - no matching RXFILL confirmation within 10 days (E3)



5

Unlike RXFILL, presumed NoFill events *were* used to trigger an active alert to prescribers, either directly to the prescriber or via surrogate users.

Because of the clinical and legal implications of NoFill alerting, meetings were held with UHMP administrative staff and risk management legal counsel to develop a UHMP practice policy for responding to NoFill alerts. Also, because of the significant *workflow* implications of both direct prescriber- and surrogate-based processing of these alerts, detailed training materials were developed and each of the nine practices was visited prior to go-live to review these with the office managers (see RXFILL / NoFill training materials and copies of relevant UHMP electronic alerts in Appendix C). Feedback from those visits affirmed both the anticipated clinical desirability of NoFill alerting and the feasibility of recommended NoFill processing workflow. Note that no formal UHMP practice policy document around RXFILL / NoFill was produced, but the agreed upon policy was reflected in the recommended workflow and training materials.

UHMP risk management counsel requested that OnCallData™ publish a weekly report indicating any open or unresolved NoFill alerts, as an additional means of helping to ensure that none of these went untended. We agreed that this would be prudent, and passed on the request to InstantDx. However, no such logs were ever produced by InstantDx during the test (presumably due to resource availability).

A follow-up survey tool was developed to assess user experience with RXFILL (see Appendix D).

#### Prior Authorization<sup>8</sup>

According to the original project proposal, five measures were outlined related to Prior Authorization (Prior Auth) testing:

- 1. Are the right data being sent? Are they usable / accurate?
- 2. Are the data well-understood at all points of the transaction? How long does it take?
- 3. How does the transaction interoperate with other initial and with foundation standards?
- 4. How do physicians / nurses / pharmacists feel about the Prior Authorization transaction?
- 5. Are there workflow impacts of the Prior Authorization transaction at the clinic or pharmacy?

We were able to perform a production test of Prior Auth and address all five of these measures with the exception of obtaining feedback from pharmacists or assessing the impact on their workflow

As with RXFILL, actually accomplishing a Prior Auth production test appeared to be a very unlikely event until quite late in the project. In this instance, the problem was finding a willing health plan (or its PBM) testing partner. As with pharmacies in the case of RXFILL transaction engineering, PBMs did not want to undertake costly engineering to enable their systems to receive and send electronic Prior Auth requests and responses, all for a pilot test of a standard with an uncertain future.

Pilot Testing of Electronic Prescribing Standards

<sup>&</sup>lt;sup>8</sup> See Section 4.2 of NCPDP Pilot Guidance Document (X12 278 Healthcare Services Review, X12 275 Additional Information to Support HC Services, HL7 Drug Prior Auth Attachment)

RxHub largely solved this problem by creating an intermediating infrastructure specifically for these pilots that essentially eliminated the need for technical Prior Auth transaction engineering by a participating health plan (or its PBM). In late summer 2006, when this new fact was understood, we re-approached Medco. Medco represented the most logical testing partner given their relevance in the Northeast Ohio market coupled with their founding relationship with RxHub. While Medco expressed interest in supporting a Prior Auth test, they felt that they would be unable to because their Prior Auth flags were not scheduled to be merged into their formulary files – distributed through RxHub – until early in 2007. These flags are necessary to inform the e-prescribing vendor that a particular drug has a Prior Auth requirement when that drug is selected during the prescribing process and are a prerequisite for any additional Prior Auth testing.

In September, we learned that Anthem (Wellpoint) was working towards participation with RxHub's Master Patient Index (MPI) beginning, conveniently, with their Ohio covered lives. We were already working with Anthem around access to claims data for our safety and cost analyses, and approached them in September about conducting a production Prior Auth test with us. After weeks spent helping (with RxHub's support) Anthem's Cincinnati-based Prior Auth team understand the work involved in preparing for the relevant Prior Auth forms for specific drugs and the workflow modifications required on their end during the actual test, they agreed to participate. This agreement did not occur until late October.

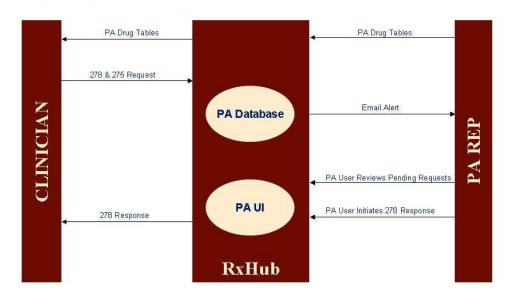
Once Anthem agreed to participate, we still needed to obtain a commitment from InstantDx to build the necessary transaction capabilities and make related application changes to support the test. InstantDx agreed, and a December 4<sup>th</sup> go-live was targeted for a 3-4 week production test and post-test evaluation in early January.

The Prior Auth test was architected according to RxHub's "unsolicited" model (see Figure 5 below). Under this model, Anthem converted the questions for the eight drugs to be tested into the format designated by RxHub, so that the questions could be incorporated into and transferred with the Anthem formulary file via the Formulary File transfer initial standard. Formulary matching during a prescribing session is predicated upon a prior successful eligibility check against RxHub's MPI (X12 270 request with a 271 response). This is why it was necessary for Anthem to begin participating with RxHub's MPI in order for us to conduct a Prior Auth test with them. This also presents a natural opportunity to assess interoperability between a foundation (X12 270/271 eligibility check/response) and two initial standards (formulary file transfer and Prior Auth).

<sup>&</sup>lt;sup>9</sup> Celebrex, Nexium, Provigil, Lyrica, Viagra, Mobic, Crestor and Vytorin

Figure 5: Prior Auth Unsolicited Model

#### **Production test planned with Anthem 12/06**



When a UHMP prescriber selects one of the Prior Auth drugs being tested for an Anthem patient (see previous footnote for list of 8 drugs tested), the Prior Auth flag in the formulary file alerts the user to the Prior Auth requirement for that drug. Under the unsolicited model, the relevant questions appear on the screen within OnCallData<sup>TM</sup>. The questions can be answered in the e-prescribing software and submitted electronically. The submission generates an X12 278 transaction with a 275 attachment, the latter containing the data related to the specific questions and responses. This transaction is sent to RxHub, which presents the relevant data from the transaction on a dedicated Prior Auth Portal, for review by a member of the Anthem Prior Auth team. Once reviewed, an authorization or denial can be submitted via the Portal back to OnCallData<sup>TM</sup> (via a 278 response transaction). Under this model, InstantDx and RxHub had to undertake transaction engineering and testing. Anthem was not directly involved in any engineering related to their internal Prior Auth processing systems.

While not directly related to standards testing, it is important to understand the Prior Auth review workflow – along with modifications to accommodate the test – at Anthem. Under normal (i.e., pre-test) circumstances, Anthem receive Prior Auth requests from physicians' offices via fax. The received fax is integrated (via a cold feed) into Anthem's internal Prior Auth request processing system, and remains available for review (electronically) throughout the review process. Once an authorization or denial decision has been made by Anthem, the decision is communicated back to the requesting physician / practice via fax.

Understandably, Anthem wished to maintain this workflow to the fullest extent possible during the test. Accordingly, they asked InstantDx to have OnCallData<sup>TM</sup> generate a matching fax directly to the Anthem Prior Auth Department in Cincinnati for every X12 278 Prior Auth request transaction sent from OnCallData<sup>TM</sup> to the RxHub Prior Auth portal, and InstantDx agreed to do this. (See Appendix E for samples of the faxes generated by OnCallData<sup>TM</sup>.) Anthem then planned on using the fax – not the transaction as represented on the RxHub portal

– to trigger and support the review process, exactly as they normally would. The only difference was that the faxed request – which otherwise was formatted to look like any other manually transmitted faxed Prior Auth request – was marked (by OnCallData<sup>TM</sup>) to indicate that it was related to the pilot test. Specifically, the OnCallData<sup>TM</sup>-generated faxed requests were marked – in large, bold typeface – with "ePA Pilot" in the upper right-hand corner of the fax (see Appendix E).

According to this workflow plan, an Anthem Prior Auth team member would only log onto the RxHub Prior Auth portal *after* a marked (faxed) request had been processed and an authorization or denial decision had been made. The portal was then used to locate the electronic request (X12 278 w/ 275 attachment) that matched the fax and, once located, trigger the X12 278 response communicating the authorization / denial decision back to OnCallData<sup>TM</sup>. The portal was thus *not used by Anthem to review incoming requests* and trigger Anthem's internal review process; instead, it was *only used to communicate the authorization decision back to OnCallData*<sup>TM</sup> *electronically*.

In keeping with their desire to maintain their usual Prior Auth review workflow in spite of the transaction testing, Anthem would continue to fax the authorization / denial response back to the requesting physician / practice even though an electronic response (via the RxHub portal) would be forthcoming. Indeed, they planned on faxing responses immediately upon completing a review, whereas they planned on logging onto the RxHub portal (to trigger the corresponding electronic response, as described above) *only twice daily*. We worried about the potential resulting ironic practice-side experience of sending an electronic Prior Auth request via OnCallData<sup>TM</sup> and then receiving a faxed response hours before receiving the corresponding electronic response back into OnCallData<sup>TM</sup>. Moreover, given OnCallData<sup>TM</sup> application development time constraints, the only way that an authorized prescription could be released (routed) to the dispensing pharmacy from OnCallData<sup>TM</sup> was by receipt of an electronic authorization from Anthem (via the RxHub portal). In other words, the practice would not be able to take action on an authorizing fax from Anthem until the corresponding authorizing transaction had been received. (These concerns did not materialize; see Results below.)

One major advantage of the parallel fax-based Prior Auth process described above was that production "electronic" Prior Auth processing between UHMP and Anthem could continue beyond the pilot test, even if RxHub took down the Prior Auth portal (as they planned on doing). The only difference would be that there would be no 278 response transactions and that InstantDx would have to add a manual prescription release trigger into OnCallData<sup>TM</sup> for authorizations received by fax.

The planned prescriber-side workflow around electronic Prior Auth was relatively straightforward: when a user (prescriber or surrogate) selects a patient to begin a prescription, OnCallData<sup>TM</sup> initiates (opaque to the user) an eligibility check (X12 270) against RxHub's MPI. Anthem patients (as of early December '06) should return a positive eligibility response (X12 271) containing Anthem-specific prescription plan identifiers for that patient; these identifiers are then used to invoke the relevant formulary data from the formulary file previously downloaded into OnCallData<sup>TM</sup> from RxHub; if one of the eight drugs being tested is selected for prescribing for an Anthem patient, OnCallData<sup>TM</sup> will display for the user not only that the drug

has a Prior Auth requirement, but also the specific Prior Auth questions for that drug; the questions can be answered at that time directly on the screen, or, if the user is a surrogate, printed to be reviewed with the authorizing prescriber (with the question responses to be entered later by the surrogate); once the answers have been entered into OnCallData<sup>TM</sup>, the Prior Auth request is submitted from OnCallData<sup>TM</sup> (X12 278 with attachment to RxHub Prior Auth portal, plus a simultaneous parallel fax directly to Anthem Prior Auth team).

The production Prior Auth test began slightly behind schedule, on December 10<sup>th</sup> and ran through the 2<sup>nd</sup> week in January (approximately 5 weeks). Given all of the *totally new* moving parts involved (Anthem participation in RxHub's MPI, converting Prior Auth questions to appropriate format for inclusion in formulary file, substantial application development by InstantDx, transaction engineering and certification between InstantDx and RxHub, workflow training at Anthem and alerting of dozens of UHMP practices), the fact that a production test occurred at all was nothing short of a minor-miracle.

To maximize the likelihood of seeing adequate Prior Auth transaction volume, given such a short testing time frame, eight drugs were selected for testing (noted in footnote above). Also, the functionality was made available for *all* of the non-pediatric UHMP e-prescribing practices (including specialty practices), not just the 18 that participated in Stage 1 of the project. Again, this was done in order to maximize volume in support of a meaningful test. Pediatrics practices were excluded because of the selected drugs' limited relevance to pediatric patients.

Because of the large number of practices involved, the lack of lead time, and the relatively straightforward application user interface and accompanying workflow, we did not undertake any on-site training for the Prior Auth test. A UHMP electronic "alert" was sent to all of the practices one week before go-live, and followed up with a reminder several days later. In the judgment of the project team, the alert (see Appendix F) contained enough detail to constitute "training."

A follow-up survey tool was developed to assess user experience with Prior Auth (see Appendix G).

#### Medication History (RXHREQ, RXHRES)

The measures and methodology to be tested surrounding Medication History transfer were not addressed in the original proposal, as it was not clear at the time that this standard would be moved from a proposed Foundation Standard to an Initial Standard.

Prior to the beginning of this pilot study, OnCallData<sup>TM</sup> supported Medication History transfers through RxHub from Medco, Express Scripts, and Caremark. Anthem-covered lives were added to RxHub's MPI in October of 2006. As noted earlier, successful RxHub prescription history

Pilot Testing of Electronic Prescribing Standards

<sup>&</sup>lt;sup>10</sup> Even though "testing" for the purposes of the pilot was completed in mid-January, the Prior Auth environment remains in production.

<sup>&</sup>lt;sup>11</sup> Anthem eligibility checking via RxHub's MPI, along with medication history transfers linked to those eligibility checks, did not become available in production with RxHub until late in the first week in December (just in time for our Prior Auth test)

transfers were occurring in over 50% of UHMP prescribing encounters, but users looked at the resulting information less than 1% of the time. Feedback from inquiries made during our Stage 1 site visits strongly suggested that lack of awareness that the feature was available was at least partly responsible for this low utilization.

We planned an intervention for the fall, the primary purpose of which was to attempt to increase user adoption of the OnCallData<sup>TM</sup> prescription history transfer feature that appeared to already be working well from a technical perspective, and assess user experience. We also seriously considered a secondary aim – namely, to assess the impact of viewing transferred prescription history on the likelihood of prescription drug regimen changes occurring on the date as the viewing event (e.g., a new drug prescribed, an old active drug discontinued, or the dose of an active drug changed). However, we felt that this latter aim was not feasible and thus did not pursue it.<sup>12</sup>

Purely by happenstance (i.e., not related to a project requirement or any planning by us), InstantDx completed engineering with SureScripts for Medication History transfers from SureScripts' new (August 2006) prescription repository – and moved this new feature into OnCallData<sup>TM</sup> production at UHMP – at the same time that we conducted our intervention. Also at the same time (and also not by project design), some enhancements were introduced to the OnCallData<sup>TM</sup> user interface related to transferred prescription history (for instance, users were able move selected items from the transferred prescription history list onto the active medication list within OnCallData<sup>TM</sup>). Importantly, there was nothing in the new user interface introduced at UHMP that attempted to help users reconcile partially overlapping prescription data from RxHub and SureScripts.

While these changes (adding SureScripts as a prescription history source and making minor modifications to the display of transferred prescription history) presented an interesting opportunity for assessment, we were concerned that they could confuse our evaluation, the primary aim of which was to assess the impact of a training intervention on user adoption of *existing* functionality. Moreover, we were not contracted with SureScripts to do any testing around Medication History, so it was unclear that we would be able to acquire transaction metrics from them around this new implementation (and, as it turns out, we were not able to). Lastly, the changes did nothing to address our primary concern with the usability of the transferred prescription history report within OnCallData<sup>TM</sup>: individual prescription claims from RxHub are merely listed in reverse chronological order, making it difficult for users to get a quick summary view of unique drugs taken by a patient in the past year. If anything, we were concerned that interspersing SureScripts' data into the report would exacerbate this usability issue, especially without any companion attempt to resolve (for the user) any overlapping (i.e., redundant) RxHub and SureScripts' prescription history data.

<sup>&</sup>lt;sup>12</sup> Structuring the intervention to facilitate such an evaluation might have been feasible − perhaps as a cluster randomized trial, as would the data acquisition (entirely from OnCallData<sup>TM</sup> logs). However, given our experience over the summer with a much longer than expected IRB process for Stage 1, we did not feel that there was sufficient time for study planning for this aim and for obtaining related IRB approval. Moreover, we were also experiencing considerable difficulty with anything but the simplest reporting from InstantDx; expecting the complex reporting required assessing the prescription changes noted above would have been extremely risky.

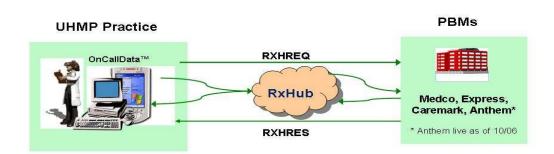
Additional detail about OnCallData<sup>TM</sup> prescription history transfer capabilities follows:

OnCallData<sup>TM</sup> requests (RXHREQ) medication history data from RxHub using the prescription benefit plan and member ID data received from the prior (X12 271) eligibility response from RxHub (see Figure 6). As implemented by InstantDx, the RXHREQ to RxHub is automatically triggered within OnCallData<sup>TM</sup> immediately upon receipt of a positive X12 271 response from RxHub (e.g., a response *other* than a "patient not found").<sup>13</sup> From the prescriber's (or surrogate user's) perspective, the transferred prescription history is available for viewing within seconds of selecting a patient within OnCallData<sup>TM</sup> to begin a prescription for that patient.

In October of 2006, OnCallData<sup>TM</sup> added medication history transaction capabilities with the new SureScripts prescription repository. In Northeast Ohio, the SureScripts repository is updated daily with dispensed or picked up<sup>14</sup> prescription data from CVS, Walgreens and Rite Aid pharmacies. This initial standard functions by pharmacies transferring prescription history information to SureScripts to be stored, and then OnCallData<sup>TM</sup> requests the information at the initiation of an e-prescription. There is no eligibility check involved with this request.

## Figure 6: RxHub-mediated Medication History Transactions

Initial Standard: Medication History (SCRIPT 8.1): OnCallData™ requests prescription history via RxHub, using prescription plan patient identifiers pulled from prior eligibility response (X12 271). RxHub routes request to PBM, which returns paid prescription claims; RxHub acts as pass-through (i.e., no repository involved). During the months of June thru September 2006, there were approximately 46,000 prescription history transfers between OnCallData™ and RxHub, but only approximately 500 views of the transferred history by users.



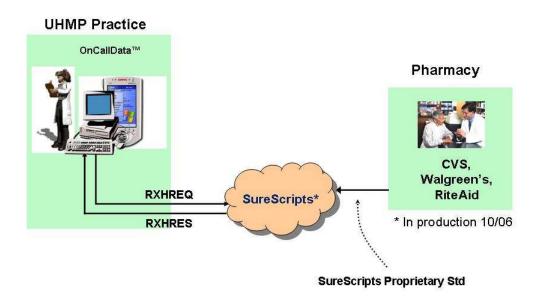
1

<sup>&</sup>lt;sup>13</sup> This particular application "workflow" for triggering Medication History request transactions has implications for obtaining patient consent, considered in Discussion section.

<sup>&</sup>lt;sup>14</sup> See RxFill section for distinction between dispensed and picked up data flags

#### Figure 7: SureScripts-mediated Medication History Transactions

Initial Standard: Medication History (SCRIPT 8.1): OnCallData<sup>™</sup> requests prescription history from SureScripts prescription repository, which is populated with filled (or picked up) prescription data directly from participating pharmacy chains (via a proprietary SureScripts messaging format). Unlike the RxHub-mediated request, there is no prior eligibility check involved, thus no 270/271 interoperability issues at play. That said, SureScripts uses core patient data elements in the RXHREQ (last name, first name, DOB, zip code, gender) that are similar, (possibly identical) to the elements used by RxHub for its patient matching during an eligibility check, and both SureScripts and RxHub use Initiate's MPI.



Prior to our Fall 2006 Medication History production test (described further below), transferred prescription history was rarely viewed by prescribers or surrogates: even though it was typically available within OnCallData<sup>TM</sup> over 13,000 times a month as the result of a successful (and automatically triggered) RXHREQ and matching RXHRES transaction, UHMP users would only view the results just over 100 times a month. In other words, user adoption of this feature was only around 1%.

The actual OnCallData<sup>™</sup> application user interface seen by UHMP users (after the SureScripts data source and minor user interface upgrade described above) is shown below in Figure 8 and 9. Figure 8 shows how the "PBM/Retail History" button on the main patient demographic screen, when clicked, triggers the viewing (on screen) of the prescription history data retrieved earlier – (possibly only seconds earlier) – via the RXHREQ / RXHRES transactions represented in Figures 6 (RxHub) and 7 (SureScripts) above. The report is partially shown in Figure 8 with an expanded view in Figure 9. The examples shown only contain prescription data from RxHub (SureScripts data, when available, would be interspersed with the RxHub data, chronologically,

on the report). The actual RXHREQ transaction to RxHub occurs automatically after a positive eligibility response (X12 271) is received from RxHub (the latter having been triggered by the patient selection event in OnCallData<sup>TM</sup>), while the RXHREQ transaction to SureScripts always occurs automatically after a patient selection event (e.g., there is no antecedent eligibility check required). The PBM/Retail History button *only becomes active if a non-empty RXHRES is returned* from either RxHub or SureScripts. Lastly, RXHRES only contains the first 50 prescription events (per source); users have to manually trigger additional transactions to pull more.

Figure 8: Button Trigger for Viewing Transferred Prescription History in OnCallData<sup>TM</sup> See text for explanation; intervening consent alerting screen not shown

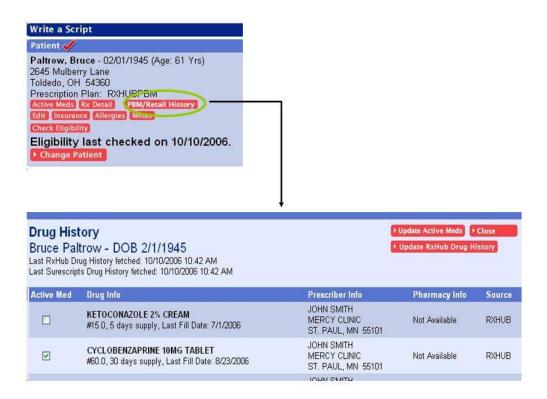


Figure 9: Expanded View of Transferred Prescription History in OnCallData<sup>TM</sup> In this example, only RxHub data is shown.



Not shown here is an intermediate consent alerting screen that appears immediately after the PBM / Retail History button is clicked by the user. This screen warns the user that patient consent is required for viewing the transferred prescription history, although no actual consent documentation or other action by the user is required to proceed to the next screen other than acknowledging the alert.<sup>15</sup>

For our Medication History test, nine practices were chosen to receive training on the existence and capabilities of the Medication History Transfer function. These are the same nine practices that participated in the RXFILL pilot test (see RXFILL Methods section for description of the practices). The production test took place between November 1, 2006 and December 31, 2006. In October of 2006, all nine practices were visited in person to explain the functionality to the practice manager. All practices managers were shown how to access the medication history and were given an explanation of available information. Copies of the training materials can be found in Appendix C.

<sup>15</sup> RxHub contractually requires vendors to ensure that adequate patient consent has been obtained prior to that vendor requesting a prescription history transfer; RxHub and their PBM participants do not believe that existing relationships between patients and the health plan or PBM adequately cover consenting for such a transfer, thus the

extra consenting requirement; SureScripts does not have a similar requirement, since the pharmacies participating in its prescription history repository believe that patient consent for prescription history transfer *is* covered under the existing relationship between patients and pharmacies.

The purpose of this test was to increase awareness and utilization of the Medication History functionality. Therefore, we asked the nine test practices to print patient Medication History whenever available at the time of a patient visit, and attach it to the chart for viewing by the treating physician. This usually meant that the MA or nurse rooming the patient would have to log in to OnCallData<sup>TM</sup>, select the patient within OnCallData<sup>TM</sup>, and then wait a few seconds to see if the PBM / Retail History button became active, and then click on the button, acknowledge the consent alert screen, and print the prescription history report. This workflow was substantially different for them in that they normally would not log into OnCallData<sup>TM</sup> and select a patient during a patient visit unless some prescribing activity was requested by the physician, usually later in the visit.

A follow-up structured interview form was developed and administered in mid-January (see Appendix D).

# Stage 3: Laboratory Testing of Initial Standards (Structured Sig, RxNorm)

## Structured Sig

The original measures outlined in the proposal included:

- 1. Are the right data being sent? Are the data usable and accurate?
- 2. Are the data well-understood at all points of transactions that incorporate Structured Sig?
- 3. How does the transaction interoperate with other initial and with foundation standards?
- 4. How do physicians / nurses / pharmacists feel about Structured Sig? Do they even notice?
- 5. Are there any workflow impacts of Structured Sig? Is it easier or harder to specify the Sig?
- 6. Does Structured Sig make it easier / harder to make a mistake when specifying the Sig?

This production test addressed the first two questions. Unfortunately, because of the nature of the test, the last four questions could not be addressed.

This laboratory test was a joint effort between this pilot and the RAND Corporation pilot. This test was executed by representing a sample of prescriptions using the proposed 14 segments and 128 data fields in the Structured and Codified Sig format. The purpose of this test was to determine the percent agreement between experts in mapping the Sigs.

The RAND Corporation obtained de-identified Sig strings from 10,000 SCRIPT new prescription messages that had been transmitted from the Allscripts ePrescribing application to retail pharmacies via the SureScripts Network in April, 2006. After normalizing these strings to remove minor variations due to spaces, punctuation, and common spelling errors, we then rank-ordered the unique Sig strings based on their frequency of occurrence in the sample. From this list of unique Sig strings, we selected a purposive sample of 45 strings for mapping into the Structured and Codified Sig format (Table 15). Thirty four of these strings were selected such that, in aggregate, they would make use of as many fields as possible within the Structured and

Codified Sig standard. These selections were then supplemented by including the 3 most common Sig strings in the sample and an additional 8 Sig strings that were selected at random.

Table 15: Free Text and Rank of Sigs that were Mapped

Table 13. The Text and Rank of Sigs that were Mapped		
Sig Free Text	Rank of Sig String	Repeats Used*
TAKE 1 TABLET TWICE DAILY	2	
TAKE 1 TABLET DAILY AS DIRECTED	3	
USE AS DIRECTED	13	
TAKE 1 TABLET TWICE DAILY WITH MEALS	15	
TAKE 1 TABLET 4 TIMES DAILY	38	
TAKE 1 TEASPOONFUL TWICE DAILY	76	
TAKE 1 TABLET AT ONSET OF MIGRAINE. MAY REPEAT ONCE AFTER 2 HOURS. MAX10 MG/DAY	323	2,2,3
TAKE 1-2 TABLETS BY MOUTH EVERY NIGHT AT BEDTIME	339	1,1,3
INSTILL 1-2 DROPS IN AFFECTED EYE(S) EVERY 2 HOURS WHILE AWAKE FOR 2 DAYS, THEN EVERY 4 HRS FOR NEXT 5 DAYS	356	2,3
1 GRAM IN WATER X ONE	374	2,0
APPLY 1 INCH 3 TIMES DAILY apply thinly to diaper rash are three times a day	410	
SPRAY 2 SQUIRTS ONCE DAILY In each nostril after saline cleansing spray	598	1,1,2
APPLY THIN FILM TO AFFECTED AREA(S) ONCE DAILY	622	.,.,_
TAKE 1 TABLET 30-60 MINUTES PRIOR TO BREAKFAST ON AN EMPTY STOMACH. DO NOT LIE DOWN AFTER TAKING MEDICATION	662	1,2,4
TAKE 1 TABLET 3 TIMES DAILY PRN As needed	1229	1,4,4
TAKE 1 TABLET TWICE DAILY take as needed for Urinary Incontinence	1412	
TAKE ONE TABLE SL THREE TIMES A DAY AS NEEDED FOE ABD PAIN	1660	
Apply to scalp & message in. Rinse off in 10 min. Repeat. Use Twice Weekly	2166	1,3,5
TAKE 4 TABLETS DAILY except for Friday take 5mg	2168	2,2,2
TAKE 1 TABLET DAILY EXCEPT ON THURS, TAKE 1/2 TAB	2169	2,2,3
TAKE 1 TABLET AS DIRECTED 7.5 mg Sa,Su 5 mg all others	2170	3,4,5
take 10 mg mon/wed/fri; take 7.5mg on all other days	2171	2,4,5
Take 1/2 tablet (2.5 mg.) daily, except on Thursday, take 1 tab	2172	1,2,3
Take 1 tablet Tues, Thurs, Sat. Take 1/2 tablet all other days	2173	2,5
TAKE 1 TABLET daily, except one and one half on Saturday	2174	2,2,2
TAKE 1 TABLET 6 DAYS PER WEEK AND 1/2 TABLET 1 DAY PER WEEK	2178	2,2,2
Take 1 tab the night before the CT scan. Take 1 tab 1 hr prior to CT scan with 50 mg benadryl as directed	2183	2,2,6
TAKE 1 TABLET TWICE DAILY for 5 days and PRN thereafter	2188	1,2,3
TAKE 1 TABLET Q.D. P.C. FOR 5 DAYS, 1 BID PC FOR 5 DAYS, 1 TID PC FOR5 DAYS, THEN 2 BID PC	2193	4,4,4
APPLY AND RUB IN A THIN FILM TO AFFECTED AREAS TWICE DAILY.(AM AND PM). for up to one week then stop	2194	1,2,3
Use one unit dose every 4 hours. Add one unit dose of Ipratropium toeach treatment	2194	1,1,3
TAKE 1 TABLET 1 TIME ONLY. Please delivery	2198	1, 1,0
INHALE 2 PUFFS EVERY 4 HOURS AS NEEDED AND TEN MINUTES PRIOR TO	2130	
EXERCISE	2200	2,2,2
INHALE 1-2 PUFFS Q2-4 PRN	2201	3,3,3
TAKE 1 TABLET EVERY 8 hrs. for 7 days	2204	

TAKE 2 TABLETS INITIALLY, THEN 1 TABLET EVERY 2 HOURS. MAXIMUM 10 TABLETS IN 24 HOURS	2205	2,3
PLACE 1 TABLET AS DIRECTED PRN one tab under tongue every 5 min until pain gone. NO MORE THAN 3 tabs total in 15 min. If chest pain persist	2211	2,2,6
USE 1 UNIT DOSE EVERY 6 hrs w/ svn prn	2213	1,1,2
1 per wrist q 6 hrs. prn nausea, not if sleepy and lethargic. Individual syringes	2214	1,1,4
25mg Top q6h PRN vomiting apply to wrist	2215	1,1,2
1 dose to rub on wrist q6h prn nausea/vomiting	2216	
PLACE CONTENTS OF 1 LEVEL SCOOPFUL IN GLASS. ADD 6 OUNCES OF		
WATER.STIR TO UNIFORM CONSISTENCY AND DRINK	2217	1,5

An Excel spreadsheet was created for mapping individual Sig strings into the key fields within the Structured and Codified Sig format. For each of the standard's 14 segments, the spreadsheet provided cells for representing each field except for the fields that would contain a controlled vocabulary code, code system identifier, or code system version. In total, the spreadsheet provided for using 45 fields. Since a definitive list of SNOMED codes for each field had not yet been completed by the task group, we asked expert reviewers to map Sig strings using the terms that they would expect to SNOMED contain for each field. Four reviewers were selected based on existing collaboration in our coalition plus one expert on the SNOMED coding system. Three reviewers are pharmacists or PharmDs who are members of the NCPDP Sig Task Group and one reviewer is employed by RxHub.

One of the "mappers", a pharmacist who was involved in creating the Sig standard, then used the Excel spreadsheet to create a reference mapping for all 45 Sig strings. The mappings for 3 Sig strings from the sample were selected for use as low-, medium-, and high-complexity examples of the mapping task. The four volunteers noted above were then given 21 of the remaining 42 Sig strings to map, assigned at random such that each Sig was mapped by two volunteers in addition to our own pharmacist expert.

We analyzed the results of this exercise to compare the representations generated for each Sig string both qualitatively and quantitatively to determine whether different reviewers mapped the Sigs identically and if not, to identify areas of discrepancies. To quantitatively analyze the degree of agreement in the representation of each Sig, the spreadsheets were "cleaned" by standardizing capitalization and removing extraneous prepositional phrases (e.g., fields containing "in a thin film" or "as a thin film" both became "thin film"). Excel spreadsheets were manipulated so the data could be imported into Microsoft Access, and queries to identify instances of agreement were executed. Each Sig had a total of 3 mappings for comparison: one by our expert pharmacist, and two by volunteer reviewers. All 3 reviewers' judgments were given equal weight in the comparison. We examined overall agreement considering all the fields that were used for a given Sig, and we also examined the agreement among reviewers within each segment for comparable Sigs.

#### **RxNorm**

In the original response to the proposal four measures of testing were outlined regarding RxNorm

- 1. Are the right data being sent? Are the data usable and accurate?
- 2. Are the data well-understood at all points of transactions that incorporate RxNorm?
- 3. How do physicians / nurses / pharmacists fell about RxNorm? Do they even notice?
- 4. Does it simplify / complicate understanding? Are there workflow impacts of RxNorm?

The final methodology addressed the first two questions; however, since this methodology was a laboratory test rather than a production test, the final two questions were not addressed.

RxNorm files are provided through two different sources: through the UMLS Metathesaurus and through zip files available through UMLS. The zip files were chosen over the UMLS because they are more up-to-date than the UMLS system by at least one month. The datasets used were the December 26, 2006 updated version of RxNorm. The zip files come with seven different files of which two were relevant: the RXNSAT (Simple Concept and Name Attributes) and RXNCONSO (Concept Names and Sources). Following instructions from Kelly Zeng and Olivier Bodenreider from the NLM, an NDC-to-RXCUI map table was produced by an inner join of the RXNSAT and RXNCONSO tables. The NDC's were parsed into label codes-product code combinations and duplicates were eliminated. The ending dataset contained the label code-product code, NDC, RXCUI, and the STR (the textual representation of concept linked to the RXCUI). This dataset was used as one of the components for the test.

The SureScripts data came from the RXRENEW requests. Before arrival, the data was stripped of all identifiable elements. The three data elements that were sent were the NDC number, the drug description, and the frequency of times the record had appeared in the dataset. The file was uploaded and set NDCs as the primary key. All NDCs were parsed into label code and product code, and unique pairs were kept. The SureScripts dataset was merged with MTHFDA to identify known medications.

The FDA's NDC Database (MTHFDA) was used as a check for false negatives. Although MTHFDA does not contain all medication concepts, whatever concepts do exist in the MTHFDA are mediation concepts. MTHFDA files are available directly from the FDA. Although there are eleven files, only the listings file was used. The MTHFDA was merged into the SureScripts file using lblcode-prodcode.

The Surescripts-MTHFDA combined dataset was merged with the RxNorm NDC-RXCUI dataset. The comparisons were then made between the RxNorm STR variable and the SureScripts drug description variable.

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<sup>17</sup> http://www.fda.gov/cder/ndc/

The contingency table is present below:

**Table 16: Contingency Table** 

Surescripts Concept is:	A Medication Concept	Not A Medication Concept
In RxNorm	True Positive (A)	False Positive (B)
Not In RxNorm	False Negative (C)	True Negative (D)

For the purposes of these tests, this study will assume that the SureScripts Medication Concept vocabulary is the reference standard that RxNorm must meet.

- True Positive: The Medication Concept from SureScripts and RxNorm match and the MTHFDA file matches (or visually verified).
- False Positive: The Mediation Concept from SureScripts and RxNorm match, but the concept is not a medication concept (machine screened by MTHFDA and manually verified).
- True Negative: The Medication Concept does not match from SureScripts and RxNorm and is confirmed not to be a medication (MTHFDA negative and manual verification).
- False Negative: The Medication Concept does not match from SureScripts and RxNorm but is verified as a medication concept (positive match in the MTHFDA or manually confirmed).

Quantitative results will be based on seven measurements. Kappa was not included as the estimated proportion of agreement would be too high.

Proportion of Overall Agreement:

Determines the proportion of cases where RxNorm and the SureScripts Medication Concepts agree:

$$p_o = A + D$$

$$A + B + C + D$$

Proportion of Specific Positive Agreement:

Determines the proportion of cases where RxNorm and SureScripts positively agree with each other.

$$P_{s+} = \frac{2A}{2A + B + C}$$

Proportion of Specific Negative Agreement:

Determines the proportion of cases where RxNorm and SureScripts negatively agree with each other.

$$P_{s+} = \frac{2D}{2D + B + C}$$

Specificity:

Determines the ability of RxNorm to correctly fail to identify concepts that are not medication concepts.

Sensitivity:

Determines the ability of RxNorm to correctly identify concepts that are medication concepts.

Sensitivity = 
$$A + B$$

Positive Predictive Value (PPV):

Determines the ability of RxNorm to correctly fail to identify concepts that are not medication concepts.

$$PPV = \frac{A}{A + C}$$

Negative Predictive Value:

Determines the ability of RxNorm to correctly identify concepts that are medication concepts.

The qualitative analysis will be based on four measures. For each misidentification or failure of identification, a pharmacist will analyze the source of the disharmony. The reports will include the following elements:

- 1. The error
- 2. Where the mismatch or nonmatch occurred
- 3. Analysis of why the error occurred
- 4. Recommendation on correction, if possible

The results of this laboratory test are summarized below in the "Results" section.

### **Stage 4: Safety and Cost Impact**

### Medication Error and Adverse Drug Events Analysis

Development of adverse drug event (ADE) monitors have been described in various inpatient studies, and rules from these prior studies were utilized to develop a computerized ADE monitor for the outpatient setting at Brigham and Women's hospital (BWH). 18 We applied a subset of the rules developed for the outpatient ADE monitor in order to identify ADEs utilizing health plan claims data. In this study, ADEs were defined as events related to medication use that resulted in patient harm and PADEs were defined as medication errors that had the potential to result in patient harm.

The detection methods utilized were non-text triggers (or rules) that search a patient's medication list and apply a set of logical rules to determine a possible ADE or medication error. In addition, other data sources are utilized for some triggers (e.g., ICD-9 codes for toxicity due to lithium, CPT codes for an esophagogastroduodenoscopy or demographic information such as gender or age).

The non-text rules were divided into 3 groups based upon the type of data utilized in the trigger: drug only, ICD-9, and drug-miscellaneous. The 1st category (drug only) involves the use of medication data; in our case NDC numbers. An example is the rule that identifies that a patient has had "warfarin toxicity". This is done by identifying patients on both Warfarin and Phytonadione. The 2<sup>nd</sup> category (ICD-9) was the utilization of ICD-9 codes, such as "poisoning by agents that affect the CV system" or "poisoning by analgesics, antipyretics and antirheumatics". The 3<sup>rd</sup> category (drug -miscellaneous) contained all the rules that involved a medication and some other (non-ICD-9 code) parameter, such as the patients' gender, age, or procedure code (CPT). Examples of these are the use of NSAIDs and a CPT code for an EGD, any female receiving finesteride, and any patient over age 65 receiving a medication in the modified Beers list 19

The final rules were identified along with rule components (NDC numbers, ICD 9 codes, CPT, etc.). These rules – which appear in the table below – were run against claims datasets from the following health plan sources: Anthem, Aetna, QualChoice and Medical Mutual.

The study subject physicians were put into the following study groups for the adverse drug event (ADE) monitor analysis.

1. UHMP e-prescribing physicians (n=97): UHMP physicians in practices recruited during the site visit portion of the study. These physicians are defined as "e-sprescribing" because they sent at least 150 prescriptions electronically in a single month prior in 2006. The date each physician met this criterion was included to enable a comparison of the number of ADE hits pre and post e-prescribing for this group.

<sup>&</sup>lt;sup>18</sup> Seger AC, Gandhi TK, Hope C, et al. "Development of a Computerized Adverse Drug Event (ADE) Monitor in the Outpatient Setting." http://www.ahrq.gov/downloads/pub/advances/vol2/Seger.pdf <sup>19</sup> Smith DH, Perrin N, Feldstein A, et al. "The Impact of Prescribing Safety Alerts for Elderly Persons in an

Electronic Medical Record." Arch Intern Med. Vol 166, May 22, 2006.

- 2. UHMP non-e-prescribing physicians (n=140): UHMP physicians in practices recruited during the site visit portion of the study who did not write/send at least 150 prescriptions electronically for any given month.
- 3. Control Group physicians (n=82): Physicians practicing in the control groups recruited for site visit participation. The physicians did not have access to electronic prescribing software.

The claims data from the health plans was provided at the DEA level. A physician was assigned to one of the three groups above based on their DEA number. Because encounter data from Medical Mutual and QualChoice had only a member identification number, it was not possible to link a member to a provider. As such, these data could not be mapped into one of the three groups discussed above. Data provided by Aetna did not contain any claims for control group physicians.

The tables presented in the Results section report the total number of ADE hits by UHMP and control group physicians and also look at number of ADE hits pre and post e-prescribing for the UHMP physicians classified as e-prescribers.

**Table 17: ADE Triggers** 

Trigger Type	Trigger Name	ADE or PADE
2 or More Drugs	Warfarin Toxicity(Receiving Phytonadione AND Warfarin)	ADE
Drug/Lab - Drug-Misc	Drugs contraindicated in Pregnancy	PADE
Drugs/Misc.	Drug/Procedure: NSAIDs /Cox2 /EGD	ADE
Drugs/Misc.	Drug/Age- modified Beers list and age greater than 65	PADE
Drugs/Misc.	Drug/Gender - female receiving Finasteride	PADE
ICD-9 Code	Seratonin Syndrome	ADE
ICD-9 Code	Neuroleptic Malignant Syndrome	ADE
ICD-9 Code	Delirium (drug induced)	ADE
ICD-9 Code	Aspirin Gastritis	ADE
ICD-9 Code	Poisoning by agents that affect the CardioVascular system	ADE
ICD-9 Code	Dermatitis due to internal substances	ADE
ICD-9 Code	Urticaria Contact	ADE
ICD-9 Code	Poisoning by psychotropic agents	ADE
ICD-9 Code	Poisoning by analgesics, antipyretics and anti- rheumatics	ADE
ICD-9 Code	Poisoning by agents that affect blood	ADE
ICD-9 Code	Poisoning by antibiotics	ADE
ICD-9 Code	Poisoning by other anti-infectives	ADE
ICD-9 Code	Poisoning by hormones and synthetic substances	ADE
ICD-9 Code	Poisoning by anticonvulsants and anti-parkinsonian	ADE
ICD-9 Code	Poisoning by sedatives and hypnotics	ADE
ICD-9 Code	Poisoning by other central nervous system depressants	ADE
ICD-9 Code	Poisoning by central nervous system stimulants	ADE
ICD-9 Code	Poisoning by drugs primarily affecting the ANS	ADE
ICD-9 Code	Poisoning by drugs primarily affecting the GI system	ADE
ICD-9 Code	Urticaria due to drug	ADE
ICD-9 Code	Poisoning by other drugs and medicinal substances	ADE
ICD-9 Code	Poisoning by drugs primarily acting on the skin and mucous membrane	ADE
ICD-9 Code	Poisoning by drugs primarily acting on smooth and skeletal muscle	ADE
ICD-9 Code	Hypoglycemia due to insulin	ADE
ICD-9 Code	Lithium or Lithium Carbonate toxicity	ADE
ICD-9 Code	Zaroxylyn Toxicity	ADE
ICD-9 Code	Reaction, Drug NEC	ADE
ICD-9 Code	Anaphylactic Shock	ADE
ICD-9 Code	Stevens Johnson Syndrome, Toxic Epidermic Necrolysis	ADE

# Cost Benefit of Formulary and Generics

# Formulary and Generics Compliance

As previously discussed, Ohio law requires that pharmacists substitute generic drugs for their brand name counterparts, when available, unless the prescriber expressly indicates "dispense as written" on the prescription. As such, we do not expect e-prescribing to have a significant impact on generic substitution rates. For our own analyses, we looked at the prescription data provided to us by a health plan partner. The data were from August 1, 2006 through October 31, 2006. Data were provided at the DEA level, enabling us to match the provider DEA number to a study (n=113) or control group physician (n=70). Within the UHMP practices, physicians were grouped according to their use of the e-prescribing application. If they met the criterion of sending at least 150 prescriptions electronically via OnCallData<sup>TM</sup> in any month of 2006, they were considered to be "e-prescribing." If they did not meet this criterion, they were considered as not e-prescribing. An analysis of variance (ANOVA) was performed to test for significant differences between means for the three groups.

Further analysis was completed on anticholestorimia drugs to compare brand name verse generic prescribing. Ratios of the brand name verse generic drugs were calculated for both the e-prescribing and non-e-prescribing physicians as well as calculating the average cost of each drug.

#### Cost Analysis

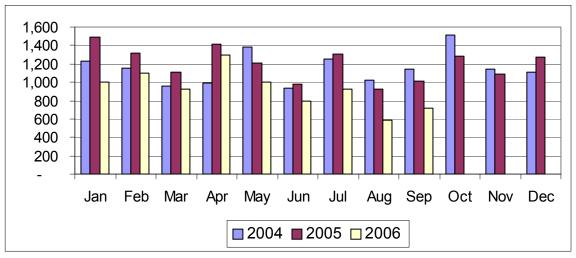
Data for the cost analyses were from the Intelligent Health Repository, or IHR<sup>TM</sup> from Wolters Kluwer Health. These data are pulled from claims adjudication transactions between pharmacies and payers and are available for over 70 percent of such transactions. The IHR data were received on 12/29/2006 and covered the period from 1/1/2004 through 9/30/2006. These data are at the DEA level, allowing for classification of the prescriber into a UHMP or control group practice. UHMP physicians were classified as follows: if they sent at least 150 electronic prescriptions in any month of 2006, they were said to be UHMP e-prescribing physicians. If they did not meet this minimum number of electronic prescriptions, they were classified as non-e-prescribing UHMP physicians. The control group physicians were members of the control group practices recruited during the site visit phase.

As an initial test of the data, data were divided into the number of prescription claims per working day per month (see Table 18). It appears that fewer prescriptions written in 2006. Since the data were compiled from a given list of DEA numbers, this cannot be attributed to a change in the number of prescribers. Additionally, Wolters Kluwers reported no significant change in clients that would explain this difference. The difference may be due, in part, to a larger proportion of prescriptions being taken to pharmacies that did not participate in the Wolters Kluwers data gathering (e.g., WalMart).

Table 18: Wolters Kluwer Prescription Claims per Month and per Work Day

		Per Work		Per Work		Per Work
	Per month	Day	Per month	Day	Per month	Day
	200	)4	200	05	200	)6
Jan	25,756	1,226	29,824	1,491	21,089	1,004
Feb	23,061	1,153	26,368	1,318	22,009	1,100
Mar	21,937	954	25,582	1,112	21,203	922
Apr	21,810	991	29,718	1,415	25,911	1,296
May	27,554	1,378	25,282	1,204	22,123	1,006
Jun	20,623	937	21,546	979	17,581	799
Jul	26,297	1,252	26,193	1,310	18,563	928
Aug	22,405	1,018	21,202	922	13,483	586
Sep	23,888	1,138	21,362	1,017	14,396	720
Oct	31,844	1,516	27,021	1,287		
Nov	24,097	1,147	22,818	1,087		
Dec	24,365	1,108	26,656	1,269		
Yearly Ave.		1,152		1,201		929

Figure 10: Wolters Kluwer Prescription Claims per Work Day per Month



The main purpose in obtaining the IHR<sup>TM</sup> data was to examine the impact of e-prescribing on prescription cost. Total cost was calculated by adding the dispensed ingredient cost to the dispensing fee (see Appendix H for the complete listing of fields in the Wolters Kluwer data). The dispensed ingredient cost is equal to the average wholesale price (AWP) less the discount negotiated by health plans. As such, differences in cost may be somewhat dependent on the health plan paying for the prescription claim. The distribution of prescription claims by payer were significantly different between the groups (Chi-square=1,7552.33, p<.001). The majority of the control group claims (53.7%) were paid for by PBMs compared to about 40% for both types of UHMP practices. About 10% of the control group physicians' prescription claims were paid by Medical Mutual of Ohio compared to 20% for the UHMP practices. QualChoice, University Hospital's insurance plan represented about 6% of claims in the UHMP physician groups and only about 2% for control group physicians.

**Table 19: Payer by Practice Type\*** 

	UHMP N	on eRx	UHMP	UHMP eRx		trol	Total
	N	%	N	%	N	%	N
PROCESSORS/PBMS	17,277	41.17	96,701	39.88	81,901	53.73	195,879
MEDICAL MUTUAL OF OHIO	8,465	20.17	48,411	19.96	15,843	10.39	72,719
EMPLOYER GROUPS	5,495	13.09	28,369	11.70	17,893	11.74	51,757
UNITED HEALTH GROUP	4,090	9.75	26,872	11.08	14,826	9.73	45,788
UNIVERSITY HOSP HLTH SYSTEMS/QUALCHOICE OHIO	2,777	6.62	15,241	6.29	3,617	2.37	21,635
AETNA US HEALTHCARE	1,920	4.57	12,797	5.28	4,962	3.26	19,679
ASSISTANCE PROGRAMS	747	1.78	6,574	2.71	3,631	2.38	10,952
WELLPOINT INC	336	0.80	2,465	1.02	5,110	3.35	7,911
CASH	407	0.97	2,800	1.15	2,275	1.49	5,482
HUMANA HEALTH PLAN INC	455	1.08	2,256	0.93	2,382	1.56	5,093
Total	41,969	100.00	242,486	100.00	152,440	100.00	436,895

<sup>\*</sup>Chi-square=17,552.33, p=.000

In an effort to compare similar prescriptions, the data were limited to only prescriptions filled at retail pharmacies and with a 30-day supply. Prescriptions sent to mail order and specialty pharmacies were excluded. The data were looked at in several ways: by practice specialty, by e-prescribing status, by year, and for prescriptions written only in September 2006. The only patient data available were gender and age range (0-19, 20-29, 30-39, 40-49, 50-64, 65+). To try to limit the analysis to a similar group patients, the data were then limited to prescriptions written for women aged 40 to 64. The results of the analyses are presented in the tables below.

# Drug Utilization Review

The data provided by Medical Mutual of Ohio for dates of service from 8/1/2006 through 10/31/2006 contained DUR edits or alerts by Provider. Medical Mutual's program administered by Medco is recognized as providing leading comprehensive and high quality Drug Utilization Review (DUR) programs. Comprehensive concurrent DUR provides patients with an added measure of safety and an enhanced quality of care. Before any prescription is dispensed, Medco's concurrent DUR comprehensively screens each prescription against a patient's prescription drug history and checks for inappropriate drug prescribing and medical conflicts or potentially dangerous interactions that may result if the prescription is dispensed. All of this information can be captured through the drug system and the dispensing pharmacist is alerted to the potentially hazardous therapy. By catching these potential interactions before a prescription is dispensed, a patient may experience safer pharmacy outcomes. The alerts are delivered by the health plan (MMO) to the pharmacy.

These data were at the DEA level allowing us to look at DUR edits by practice type (UHMP e-prescribing, UHMP non-e-prescribing, and control) and by physician specialty (family medicine, internal medicine, and pediatrics). The DUR data were limited to alerts for drug/drug

interactions and high dose. The drug interaction alert identifies when the incoming drug can potentially result in ineffective or unsafe treatment when used in combination with another drug on the patient profile. The high dose edit indicates that the prescription was written for more than the maximum recommended days supply or quantity or strength given the patient's demographic information such as age, sex, or weight.

The number of high dose and drug/drug interaction edits were summed and divided by the total number of prescriptions with the same dates of service to calculate a DUR rate per 1,000 prescriptions. Result tables are presented below.

#### Results

## **Stage 1: Site Visits**

During our site visit analyses we focused on the general characteristics effecting e-prescribing within our study group as well as the factors effecting e-prescribing adoption and workflow efficiency issues.

# **General e-Prescribing Characteristics**

There are two general e-prescribing characteristics that seem to effect adoption and efficiency at the UHMP practices.

- 1. E-prescribing application integration with a practice management system.
- 2. Flexibility in the primary user of the e-prescribing application.

#### Integration with Practice Management System

In our UHMP study group, almost all practices have integrated OnCallData<sup>TM</sup> with Concept<sup>TM</sup>. This integration is a mandatory part of the e-prescribing program at UHMP. The integration allows for demographic information to be passed from Concept<sup>TM</sup> to OnCallData<sup>TM</sup>, without having to create a separate patient profile within OnCallData<sup>TM</sup>. Several office managers pointed out that this was critical to early adoption within their practices.

There is one practice that does not have Concept<sup>TM</sup> integrated with OnCallData<sup>TM</sup> at UHMP. This practice is a large, family practice that utilizes an electronic medical record (EMR) system, which its own companion practice management system. This practice paid \$15,000 for a one-way interface between PMS component of their EMR and OnCallData<sup>TM</sup>. OnCallData<sup>TM</sup> would be updated – real time – with patient demographic data as it was entered into (or changed within) the PMS. This was the only UHMP practice that needed to incur an additional expense to establish demographic data transfer from their PMS into OnCallData<sup>TM</sup>. The fact that they did so reinforces the perceived importance of integrating the PMS with the e-prescribing software. It is important to note that no interface was built was built that transferred clinical (e.g. prescription-related) data back from OnCallData<sup>TM</sup> into this practice's EMR.

In our opinion, the integration of the PMS with OnCallData<sup>TM</sup> represents the largest threat to the generalizability of our adoption findings to truly independent, small, community-based practices. Typically, practices would need to bear both the up-front licensing costs and the cost of integrating the PMS to their e-prescribing application. The UHMP practices have had neither of these costs. The cost of PMS integration is a well-recognized and significant barrier to EMR adoption in independent practices of any size (but especially for smaller practices), and is likely a significant barrier in these practices to e-prescribing adoption as well.

#### Primary User Flexibility

One of the most important findings of our project was the high rate of dependence of prescribers on surrogate-based e-prescribing. From August through November 2006, 77 percent of e-

prescriptions entered into OnCallData<sup>TM</sup> were entered by someone other than the authorizing prescriber (also referred to as "surrogate" entry). See Table 11 for additional details.

Furthermore, surrogate-based adoption did not appear to be a transitional stage leading to directuse adoption patterns by e-prescribers who start out as surrogate-based. This finding challenges a prevalent tenet of e-prescribing adoption, namely that the best way to achieve e-prescriber adoption is by engaging surrogates first. While engaging surrogates around e-prescribing appeared to be a remarkably winning strategy for driving *practice* adoption, we found no evidence that it systematically led to ultimate direct e-prescribing by individual prescribers within that practice. If the surrogate-based workflow made sense for a practice at the beginning of an implementation, then it worked for a reason and tended to persist.

#### Phone Call and Fax Volume

All results must be interpreted with caution. Due to the nature of the collection tool and the workload of most practices, the validity of the data is suspect.

Twenty UHMP practices returned both phone and fax tally sheets. These 20 practices represented 63.75 FTE physicians. Similarly, 19 control group practices, representing 62.5 FTE physicians returned phone and fax tally sheets.

Table 20: Number of Calls per Physician per Day, Second-day Calls Only, All Call Types

	Mean	Std. Deviation	Std. Error	t-statistic	Sig. Level
UHMP	7.58	5.89	1.35	0.353	0.726
Control Group	6.90	5.75	1.35		

Table 21: Number of Calls per Physician per Day, Calls from All Five Days

	Mean	Std. Deviation	Std. Error	t-statistic	Sig. Level
UHMP	7.96	6.62	0.666	1.52	0.132
Control Group	6.67	5.08	0.53		

The means were almost unchanged between the groups when looking at the second day of data collection and all days of data collected. The e-prescribing and control group practices were not statistically different in terms of the average number of calls per physician per day.

Since little difference was observed using the data from the second day of collection compared to all five days, data from all five days were used in the remaining analyses. Data for incoming and outgoing calls were analyzed separately. The results of these analyses are presented below.

Table 22: Number of Incoming and Outgoing Calls per Physician per Day

	Practice Type	Mean	Std. Deviation	Std. Error	t-statistic	Sig. Level
Incoming Calls	UHMP	5.48	4.40	0.43	2.59	0.010
	Control	4.14	2.81	0.28		
Outgoing Calls	UHMP	1.53	1.07	0.13	-5.38	0.000
	Control	3.59	3.08	0.36		

The e-prescribing practices had significantly more incoming calls and significantly fewer outgoing calls compared to the control group practices. The higher average number of incoming calls may be associated with callbacks from the patients, who upon arrival at the pharmacy, are told by the pharmacy staff that they have no prescription for them. Instances such as this were described during many site visits to UHMP practices. While some of the practices have resolved the problem through pharmacy education, it remains a problem. Additionally, calls from the patients and/or pharmacies regarding the absence of a prescription may have been higher during the timeframe of data collection as many of the practices were still in the earlier stages of e-prescribing during the Summer of 2006.

Next, the characteristics of incoming and outgoing calls were examined. Practice staff, via the tally sheets, was asked the amount of time spent on the phone dealing with the prescription-related phone call, the source or destination of the call, the prescription issue that was being called about and whether or not a chart pull was necessary to process the call. See the tables below.

**Table 23: Differences in Time Spent on Phone** 

		INCOMING	G CALLS*		OUTGOING CALLS*			
	UHI	MP	Con	trol	UH	MP	Control	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Time Spent on Phone								
< 2 minutes	1,029	66.1	898	62.4	157	53.8	547	63.2
2 to 5 minutes	465	29.9	499	34.7	101	34.6	276	31.9
> 5 minutes	63	4.1	42	2.9	34	11.6	43	5.0
	1,557	100.0	1439	100.0	292	100.0	866	100.0

<sup>\*</sup> Chi-square significant at p<.01

The distribution of the time spent on the phone for both incoming and outgoing calls was statistically different between the UHMP and control practices. While the UHMP practices had significantly more incoming calls (Table 23), a higher proportion of these calls were under two minutes, compared to the controls (66% vs. 62%). Conversely, the UHMP practices had significantly fewer outgoing calls (Table 23) but a larger proportion of these calls took more than two minutes (46.2%) compared to the control group practices 36.9%.

Table 24: Differences in the Source or Destination of Phone Calls

		INCOMING	G CALLS		OUTGOING CALLS*			
	UHI	ΙP	Con	trol	UH	MP	Control	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Source/Destination								
Patient	1,094	69.9	1,020	68.5	92	31.7	160	19.1
Pharmacy	435	27.8	440	29.5	173	59.7	634	75.7
PBM	36	2.3	30	2.0	25	8.6	43	5.1
	1,565	100.0	1,490	100.0	290	100.0	837	100.0

<sup>\*</sup> Chi-square significant at p<.01

The difference in the distribution of the source / destination of prescription-related calls was statistically significant for outgoing calls only. The UHMP and control group practices were remarkably similar in terms of the source of incoming calls: roughly 70% were from patients, 29% from pharmacies and 2% from PBMs. For outgoing calls, the e-prescribing practices had a smaller percentage of calls to pharmacies (60%) compared to almost 76% in the control group practice. This is likely due to the fact that the practice staff can enter the prescription and send it electronically to the pharmacy rather than having to call it in. This is one of the biggest gains in efficiency related to e-prescribing.

Table 25: Differences in the Prescription-Related Issue of Phone Calls

unic 20. Differences in the 11 esemption returned 18800 of 1 hone cans									
		INCOMIN	G CALLS			OUTGOIN	G CALLS*		
	UH	MP	Con	trol	UH	MP	Control		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	
RX Issue									
New Prescription	235	15.1	222	15.1	61	21.0	256	29.2	
Renewal Prescription	1,127	72.4	1,069	72.6	141	48.5	508	57.9	
Formulary	18	1.2	25	1.7	9	3.1	39	4.4	
Prior Authorization	38	2.4	19	1.3	20	6.9	23	2.6	
Clarification	138	8.9	137	9.3	60	20.6	51	5.8	
	1,556	100.0	1,472	100.0	291	100.0	877	100.0	

<sup>\*</sup> Chi-square significant at p<.01

The two types of practices were also quite similar regarding the prescription-related issues of incoming calls. The UHMP and control group practices were statistically different regarding the issues of outgoing calls. Interestingly, the biggest difference was in the proportion of outgoing calls that had to do with a "clarification." According to the instructions sheets provided to the practices, a clarification was if the main reason for the call was some other issue or possible problem with a prescription such as legibility, dose, instructions, etc. The larger proportion of outgoing clarification calls may be related to the issue of patients showing up at the pharmacy and being told by the pharmacy staff that they have no prescription for them. This would necessitate an incoming call to the practice (from the patient or pharmacy) and perhaps a companion outgoing call to instruct the pharmacy that the prescription was indeed sent, etc.

Table 26: Differences in Charts Requested to Process Prescription-Related Phone Calls

		INCOMING CALLS									
	UHI	ИP	Con	trol							
	Number	Percent	Number	Percent							
Chart Requested?											
No	153	10.6	151	10.5							
Yes	1,293	89.4	1,287	89.5							
	1,446	100.0	1,438	100.0							

Note: Chart pull information requested for incoming calls only

The majority of incoming, prescription-related phone calls required a chart pull in both the UHMP and control group practices. The distribution is nearly identical between the practice types and not statistically different.

The number of prescription-related faxes was also compared for the practice groups. The mean of e-prescribing practices was compared to the mean for all non-e-prescribing practices.

Table 27: Prescription-related Faxes per Physician

	Mean	Std. Deviation	Std. Error	t-statistic	Sig. Level
UHMP	15.85	12.21	2.73	1.29	0.209
Control Group	10.93	11.75	2.70		

While the UHMP practices received a larger number of prescription-related faxes than the control group practices, this difference was not statistically significant.

# Adoption of E-Prescribing

Forty-five medical group practices were included in this study. Since the main variable of interest was the influence of e-prescribing of drugs on costs and quality of care, we started with 25 UHMP practices that had adopted e-prescribing and matched them with practices that have not adopted these technologies. Practices were matched on size, specialty mix and urban location. Twenty-two matched practices were recruited for the study resulting in the 45-practice sample. Some of the UHMP practices did not have full use of this technology by all of their physicians but those practices were classified as adopters. When the unit of analysis was physician level, the physician not using e-prescribing in UHMP practices were treated the same as physician in the matched practice.

The practices in our sample ranged in size from 1 to 9 FTE physicians. As shown in Table 28, the e-prescribing practices were slightly larger than the others and although all of these practices were selected because they provided primary care, there was a mix of physician specialties and one practice had at least some sub-specialists.

Table 28: Practice Size, Specialty, and Tax Classification

	Physician Mix	Size	Tax Class for Profit
UHMP Study Group (e-prescribing)	Family medicine – 5 Internal medicine – 14 Pediatrics – 6	3.60	100%
Control Group (non e-prescribing)	Family practice – 10 Internal medicine – 8 Pediatrics – 4	3.97	73%

Also as shown in Table 29, most of the practices were for-profit practices although nearly one third of the non-adopters were organized as not-for-profit practices. Most of these were owned by a hospital or hospital system although the practice physicians owned about half of the matched group practices (see Table 29).

**Table 29: Practice Ownership** 

	Hospital	Another Practice	Some of the Physicians	All Physicians	НМО	Other
UHMP	24	0	0	1	0	0
Control*	2	1	3	7	0	8

<sup>\*</sup>Not all control group practices completed a Medical Group Practice Organization Survey containing this data.

As previously noted, all of the UHMP practices have adopted e-prescribing and none of the matches have this technology (non-adopters). However, the non-adopters have some electronic-based information capacity. As shown in Table 30, 29 percent of the physicians in non-adopter practices have computer terminals at the patient care site, and 57 percent of these physicians have e-mail capabilities, although 30 percent of these practices have neither of these capabilities. Also, as shown in Table 30, the e-prescribing practices have more capacity in all of these areas than the matched non-adopters. This could suggest that there is an electronic information mentality in the practices that have adopted e-prescribing although we do not have longitudinal data and, therefore, cannot determine levels of causality.

Table 30: Proportion of Physicians in Each Practice That Have Certain Computer Capabilities at Their Patient Care Site

	Computer Terminal at Patient Care Site	Computer- based Patient Chart Data	Computer- based Rx Data	Computer- based Drug Interaction Data	Can Send E- Mail
UHMP	.38	.33	.41	.28	.90
Control	.29	.06	.02	.10	.57

To explore this "information mentality" issue further, we analyzed several additional organizational factors related to clinical information. As shown in Table 31, the practices vary significantly on several of these measures included in our study. For example, adopter practices are more likely to have physician benchmarking programs (32 percent compared to 20 percent

for non-adopters). However, there is little difference between the e-prescribing and control practices in terms of policies regulating pharmaceutical sales person visits (only about 64 to 73 percent have these policies in either group), in the identification of high cost patients (9 percent in the e-prescribing and 8 percent in the controls), or in patient satisfaction surveys (50 percent vs. 40 percent). The e-prescribing practices do collect more information on patients with chronic illness compared to the non-e-prescribing practices but have fewer physician profiling programs.

**Table 31: Practice Characteristics** 

	Ber	nchm	ark	ing		Pation Surv	ctic	n	[	Orug S Polic		}		I.D. I Co Pati	st			). Pat Chro	_			hysi Profi		
	Y	es	N	lo	Ye	es	N	Ю	Y	'es	1	lo	Υ	es	N	o	Y	es	١	0	Y	es	<b>N</b>	lo
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
UHMP	7	32			11	50			16	72.7			2	9			7	41			14	64		
Control	5	20			10	40			16	64			2	8			11	44			9	36		

Our next analysis focused on measures of physician workload. This is an important variable since time pressures can influence physician clinical decision making and patient follow-up leading to errors.

Since more nursing support staff and, especially nurse practitioners, greatly influence physician workloads, we evaluated the number of total support staff per physician in each of the practices, the number with training at the RN level, and the number of nurse practitioners. These data are shown in Table 32. The control practices have slightly more in total staff support per physician than the UHMP practices. Additionally, the control practices have more staff trained at the RN level and have more nurse practitioners both of which could provide more prescription drug help for the physicians.

**Table 32: Practice Support Staff** 

	Total Support Staff Per Physician	Total RN Staff Per Physician	Total NP Staff Per Physician
UHMP	4.89	.28	.05
Control	6.23	.88	.17

The final structural variable included in our analysis is the decision making process in the practices. The way decisions are made can be expected to influence both the adoption of technologies such as e-prescribing and the degree of use by the physicians. We used one statement to evaluate the decision-making process: the medical director and administrator make all of the administrative decisions in this practice. This question is scored on a 1 to 5 scale with 1 indicating "not at all" and 5 indicating "to a great extent." Table 33 shows the scores for the question.

**Table 33: Practice Decision Making** 

	The medical director and a administrative decis (1 to 5	• • • • • • • • • • • • • • • • • • •
	Score	Range
UHMP Study Group Practices	4.04	1-5
Control Group Practices	3.48	1-5

As shown in Table 33, the e-prescribing practices have a more centralized decision-making process. This might reflect the fact that they are owned by an external organization (hospital), although the variances in the responses from both groups indicates that the individual practices vary considerably in how decisions are made and this can be expected to influence both the adoption and use of the e-prescribing technologies.

Next we analyzed the degree of correlation among the organizational variables. If these variables are not independent, their explanatory power in the multivariate model will be diminished. As shown in Table 34, none of the variables were found to be highly correlated with others and, consequently, none were dropped from the analysis because of intercorrelation.

**Table 34: Practice Structure Correlation Matrix** 

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1	1.0000																	
2	0.3418	1.0000																
3	0.0580	-0.0090	1.0000															
4	0.3180	0.2295	0.5209	1.0000														
5	0.4621	0.2456	0.3773	0.7960	1.0000													
6	0.0154	0.2321	0.0699	0.4993	0.4079	1.0000												
7	0.4711	0.3386	0.0232	0.3429	0.3093	0.2335	1.0000											
8	-0.2168	-0.2986	0.2482	-0.0712	-0.0848	0.0646	-0.2380	1.0000										
9	-0.1269	-0.0491	0.1211	-0.2064	-0.1552	0.0804	-0.2567	0.1982	1.0000									
10	-0.0210	0.0147	0.2156	0.4582	0.4079	0.2841	-0.0371	-0.1821	-0.0793	1.0000								
11	0.0111	0.1709	0.1740	0.1946	0.0307	0.0714	0.2081	-0.3757	-0.1271	0.0922	1.0000							
12	-0.1078	-0.3668	-0.1599	-0.1505	-0.0748	-0.1585	-0.1619	0.0360	-0.0080	0.0172	-0.6242	1.0000						
13	0.1133	0.2335	-0.0114	-0.0459	0.0523	0.1037	-0.0480	0.3856	0.1540	-0.1251	-0.4099	-0.4568	1.0000					
14	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000				
15	-0.0913	0.0486	0.0712	0.0267	0.0654	0.0182	-0.0152	0.0340	0.0699	-0.0035	-0.2437	0.1752	0.0728	0.0000	1.0000			
16	-0.1197	-0.1755	0.1109	-0.0636	0.1112	-0.0433	-0.3260	0.3500	0.2604	0.1100	-0.3712	0.2735	0.1033	0.0000	0.2374	1.0000		
17	-0.2513	-0.0882	0.1924	0.0502	0.0597	-0.0095	-0.0601	0.1239	0.0278	0.0635	-0.0967	0.2076	-0.1322	0.0000	0.0236	0.2952	1.0000	
18	0.2380	0.5848	0.0620	0.0539	0.0948	-0.0461	0.0443	-0.0099	-0.2434	-0.1771	0.0448	-0.2068	0.1904	0.0000	0.1460	0.0490	-0.1278	1.0000

- l Owned by hospital
- 2 For profit
- 3 Have computer terminal at patient care site
- 4 Have computer patient data at care site
- 5 Have computer patient drug data at patient care site
- 6 Have computer drug interaction data at patient care site
- 7 Physician can send e-mail from patient care site
- 8 Total support staff per physician
- 9 Have nurse practitioners

- 10 Number of FTE physicians
- 11 Family practice clinic
- 12 Internal medicine clinic
- 13 Pediatric clinic
- 14 Multi-specialty clinic
  - 5 Patient satisfaction survey
- 6 Identify patients with chronic illness
- 17 Physician profile program
- 18 Centralized decision making

This left 26 explanatory variables for our multivariate analysis. We have over 170 observations for the model when the individual physicians are the units of analysis. However, for two of our analytic models, the practices are the unit of analysis reducing the sample size to 47 practices for the adoption of the e-prescribing technology analysis and 25 practices for the degree of implementation once the technology is adopted.

Since we have a limited number of practices in our data and 26 practice characteristics of interest, the ability of our data to identify the individual effects of each of the practice characteristic is limited. There are a number of estimation strategies that we can pursue:

- 1. We can reduce the number of practice characteristics to those that have been shown to have the strongest effects on resource use or quality outcomes in previous studies.
- 2. We can create blocks of common types of indicators (e.g., structural characteristics, practice culture, demographic characteristics of member physicians) and test the significance of each block of variable individually in the regression.
- 3. We can adopt a pure forecasting approach and use a method like step-wise regression to reduce the number of practice characteristics to a set of best predictors. This approach is not useful for analyses of causal effects, but it can be useful if one simply is trying to find the practices that have the best outcomes.
- 4. We can include all the practice characteristics and accept the fact that we have limited statistical power to detect their effects on practice outcomes.

As previously noted, in some of our analyses we have data on individual physicians, resulting in much larger sample sizes. That is a great advantage when identifying the effect of physician characteristics on the outcomes of interest, or when separating the effects of physician characteristics from the effects of practice characteristics, but those larger samples do not give us greater statistical power to identify the effect of practice characteristics.

Given the alternatives outlined above, we again reviewed the literature related to the remaining explanatory variables to assess the strength of their influence on the dependent variable of interest. All of these variables were included in the study because they have been shown to influence medical practice performance. However, four variables were dropped because others in the model were more relevant to e-prescribing adoption and use. These were 1) have benchmarking programs, 2) conduct patient satisfaction surveys, 3) the identification of high cost patients, and 4) practice tax status. Each of these areas had other, more relevant, e-prescribing variables i.e. 1) physician profiling, 2-3) the identification of patients with chronic illness (because they get more prescriptions), and 4) practice ownership. In addition, we dropped five variables that had little variance among the practices or were related to the e-prescribing technology (i.e. computer terminals at the patient care site, computer-based drug interaction data or prescription data at the patient care site, have pharmaceutical sales representative policies, and have

nurse practitioner). This left 17 practice structure variables and nine practice culture variables for inclusion in our analysis.

Since the inclusion of all of the remaining variables in a regression equation could seriously limit the statistical power, we focused on two alternatives, i.e., creating blocks of variables and entering each block separately and reducing the explanatory variables to the best predictions using step-wise regression. Organizational structure variables are included in the first block, the culture variables in the second, and the physician characteristics in the third. Separate equations were estimated using each of these approaches addressing the three main dependent variables: 1) e-prescribing adoption rates at the practice level, 2) practice-wide implementation rates after adoption, and 3) physician e-prescribing use rates within the practices that have adopted these technologies.

Multivariate Analysis

Table 35: Differences in the Cultures of Study and Control Group Practices

Logit estimates Number of obs = 38LR chi2 (9) = 23.63

LR chi2 (9) = 23.65 Prob . chi2 = 0.0049 Pseudo R2 = 0.4499

Log likelihood = 14.461046

Adopt	Coef.	Std. Err.	Z	P> *t*	[95% Conf.	. Interval]
Collegiality	-1.976903	1.772185	-1.12	0.265	-5.45032	1.496515
Information	5.21644	2.417896	2.16	0.031	.4774503	9.955429
Quality	.0364183	2.001662	0.02	0.985	-3.886767	3.959604
Management	.2041121	.9703696	0.21	0.833	-1.697777	2.106002
Style						
Cohesiveness	3.986776	2.487916	1.60	0.109	8894499	8.863002
Organizational	9007233	1.720128	-0.52	0.601	-4.272112	2.470666
Trust						
Adaptive	3.378013	2.571605	1.31	0.189	-1.66224	8.418266
Autonomy	-4.72278	2.16749	-2.18	0.029	-9.970982	4745781
Business	1.240313	1.653426	0.75	0.453	-1.000343	4.480969
cons	-17.4548	9.265015	-1.88	0.060	-35.61389	.7042966

These data indicate that practices that have adopted e-prescribing have cultures that place more value on information (have an information mentality), are more cohesive, have high levels of organizational trust, are more adaptive and have a culture that emphasizes the group over the individual physician (less autonomous). The adaptive variable is only significant at the P = .18 level but we report it because with this small sample size, it is an important finding. These are important findings for those that are attempting to expand the adoption of these technologies to other medical groups since it points to cultural traits that might influence the success of their efforts.

Our next analysis focused on the influence of the culture of the practice on physician use of e-prescribing in practices that have adopted these technologies. As shown in Table 36, three cultural traits influence use rates. Physicians in practices that have a culture that places higher values on quality and on physician autonomy have higher use rates although the quality factor is only statistically significant at the P = .13 level. An interesting finding is that physicians in practices with cultures that emphasize the importance of data have lower use rates. This could mean that these physicians are relying on other sources of information to manage their prescriptions or that e-prescribing is not considered an important information source even though there are important administrative advantages.

Table 36: The Influence of Practice Culture on Physician Use of E-Prescribing in Practices That Have Adopted E-Prescribing

Source	SS	df	MS		Number of obs	=	107
Model	3.28567373	9	.365074859		F ( 9, 97)	=	3.55
Residual	9.98827247	97	.102971881		Prof > F	=	0.0008
Total	13.2739462	106	.125225908		R-squared	=	0.2475
					Adj R-squared	=	0.1777
					Root MSE	=	.32089
% eRx Phy	Coef.	Std. Err.	t	P> *t*	[95% Co	nf. In	terval]

% eRx Phy	Coef.	Std. Err.	t	P> *t*	[95% C	onf. Interval]
Collegiality	.0216392	.1843005	0.12	0.907	3441463	.3874246
Information	6544263	.3153961	-2.07	0.041	-1.2804	0284524
Quality	.2966734	.1982756	1.50	0.138	0968489	.6901957
Management	1555893	.2102214	-0.74	0.461	5728206	.261642
Style						
Cohesiveness	2296592	.1982938	-1.16	0.250	6232176	.1638991
Organizational	1478685	.1731221	-0.85	0.395	4914679	.1957309
Trust						
Adaptive	.0656912	.2429686	0.27	0.787	4165342	.5479166
Autonomy	.3486145	.1757333	1.98	0.050	0001675	.6973966
Business	.1146181	.1290235	0.89	0.377	1414578	.370694
_cons	1.694261	.7663582	2.21	0.029	.1732522	3.21527

Table 37: The Influence of Physician Characteristics on Their Use of E-Prescribing

Source	SS	df	MS	Number of obs	=	107
Model	1.97543762	4	.493859406	F (4, 102)	=	4.40
Residual	11.4438328	102	.112194439	Prof > F	=	0.0025
Total	13.4192704	106	.126596891	R-squared	=	0.1472
				Adj R-squared	=	0.1138
				Root MSE	=	.33495

% eRx Phy	Coef.	Std. Err.	t	P> *t*	[95% Conf. Interval		
Age	.0055752	.0039342	1.42	0.159	0022282	.0133786	
Female	.1028018	.067373	1.53	0.130	0308322	.2364358	
Internal Med	2187712	.1286711	-1.70	0.092	4739898	.0364474	
Pediatrics	.0256324	.1320398	0.19	0.846	2362678	.2875327	
_cons	.2824807	.2097583	1.35	0.181	1335739	.6985253	

As shown in the above table, the only physician characteristic that is related to use of e-prescriptions in practices that have adopted these technologies is the internal medicine specialty. Internal medicine physicians are less likely to use e-prescriptions than family practitioners but pediatricians use these technologies at about the same rate as family practitioners. Physician age has no influence on these use rates but women physicians have higher rates although only significant at the P = .13 level. In this equation, the male gender and family practice specialty are left out as reference variables.

#### Stepwise Regression

Our next analyses used stepwise regression to assess the influence of the practice and physician variables on the use rates of e-prescriptions once adopted by the practice. This statistical approach provides insights into the relative influence of the variables since they compete with each other in the equations and those with less influence are removed. In the first of these analyses (Table 38) we entered the organizational culture and structure variables into the regression model with the e-prescribing use rate at the practice level the dependent variable. As shown in Table 38, this analysis identified several influential variables that were not significant in the blocked variable analysis. The most important of these are practice size, more support staff, a collegiality culture, and a strong management culture all have a positive influence on use rates at the practice level. However, the physician profiling variable which was found to be significant in the previous analysis is not found to be influential. Moreover, the organizational trust and quality emphasis culture variables now have a negative influence on use rates. This could indicate that e-prescriptions use is not viewed as a quality improvement mechanism by the physicians.

The influence of organizational trust is difficult to evaluate. There are clearly some interactions between the physicians and the practice that are captured by this variable that have a negative impact on e-prescriptions use rates. One possibility is that the trusting organization was not pressuring the physicians to use the technology.

# **Table 38: Stepwise Regression on Use Rates at the Practice Level with Structure and Culture Variables**

sw reg pct\_erx hospital\_own pracis\_m total\_phy gm ped support\_per\_phy phyprof1 > avgofcollegiality avgofinfoemphasis avgofquality avgofmgmtstyle avgofcohesiv > e avgoforgtrust avgofadaptive avgofautonomy avgofbusiness, pr(.2) (hospital\_own dropped because constant)

# begin with full model

 $p = 0.4224 \ge 0.2000$  removing information emphasis

p = 0.4168 >= 0.2000 removing autonomy

p = 0.3778 >= 0.2000 removing physician profiling

p = 0.5217 >= 0.2000 removing business

p = 0.5749 >= 0.2000 removing cohesiveness

Source	SS	df	MS	Number of obs	=	18
Model	1.1330233	10	.113302338	F (9, 97)	=	5.54
Residual	.14320438	7	.020457769	Prof > F	=	0.0166
Total	1.2762277	17	.075072221	R-squared	=	0.8878
				Adj R-squared	=	0.7275
				Root MSE	=	14303

% eRx	Coef.	Std. Err.	t	P> *t*	[95% Conf. Interval]		
Have e-mail	1.158303	.3111743	3.72	0.007	.4224926	1.894113	
Total phys.	.0842346	.0272718	3.09	0.018	.019747	.148722	
Gen med	5107376	.173794	-2.94	0.022	921695	0997802	
Pediatrics	3339364	.2275301	-1.47	0.186	8719597	.2040869	
Support staff	.0980282	.0554257	1.77	0.120	0330329	.2290892	
Adaptive	190089	.1321144	-1.44	0.193	5024899	.1223119	
Collegiality	.4054963	.1256844	3.23	0.015	.1082998	.7026927	
Organizational	7912817	.2022527	-3.91	0.006	-1.269533	31303	
Trust							
Quality	456852	.1580864	-2.89	0.023	830667	0830369	
Management	.3766759	.1293135	2.91	0.023	.070898	.6824538	
Style							
_cons	1.059997	.4268585	2.48	0.042	.0506368	2.069357	

Table 39 shows the stepwise analysis of e-script use rates at the physician level when physician variables and practice culture variables are included in the analysis.

Table 39: Stepwise Regression of Use Rates at the Physician Level with Physician and Culture Variables

. sw reg pct\_eRx\_phy age female internal\_med ped collegia infoemph qualemph mana > gest cohesive orgtrust adaptive autonomy business, pr(.2)

begin with full model

 $p = 0.8195 \ge 0.2000$  removing adaptive

 $p = 0.7529 \ge 0.2000$  removing management style

p = 0.8170 >= 0.2000 removing cohesiveness

p = 0.7647 >= 0.2000 removing quality emphasis

 $p = 0.5469 \ge 0.2000$  removing pediatrics

p = 0.5108 >= 0.2000 removing female

p = 0.4185 >= 0.2000 removing collegiality

 $p = 0.3966 \ge 0.2000$  removing age

Source	SS	df	MS	Number of obs	=	105
Model	3.6696354	5	.733927084	F ( 9, 97)	=	7.63
Residual	9.5182043	99	.096143478	Prof > F	=	0.0000
Total	13.187839	104	.126806151	R-squared	=	0.2783
				Adj R-squared	=	0.2418
				Root MSE	=	31007

% eRx Phy	Coef.	Std. Err.	t	P> *t*	[95% Conf. Interval]		
Information	3879549	.1484751	-2.61	0.010	6825617	0933481	
Autonomy	.2374612	.1410863	1.68	0.096	0424846	.517407	
Internal Med	194354	.072378	-2.69	0.008	3379677	0507403	
Business	.1694874	.0888043	1.91	0.059	0067196	.3456945	
Org. Trust	1283023	.0951421	-1.35	0.181	3170849	.0604803	
_cons	1.065327	.3890601	2.74	0.007	.2933473	1.837307	

There are three main findings from this analysis. First, it confirms some of the previous findings regarding physician specialty (internal medicine has negative coeff.), the negative influence of organizational trust, and the positive influence of physician autonomy cultures. Second, it indicates that at the physician level, a business oriented culture enhances use rates. This could indicate that physicians in these cultures believe that e-prescriptions use makes good sense from a business perspective. However, some of the variables found to be influential in the blocked analysis now were dropped out of the analysis. Physician gender has no influence and an information culture now has a negative influence.

#### Workflow Efficiency

The following is an analysis of data collected from the Prescription Renewal Workflow Interview (see Appendix A). Since the Prescription Renewal Workflow Interview was a mandatory part of each site visit, we obtained a 100 percent "response rate" for the

instrument as a whole. However, some individual questions were not answered 100 percent of the time.

With the exception of one (of 22) control practice, all of the practices in both groups had a policy allowing patient renewal requests at times other than during an actual patient visit. While this difference was actually statistically significant, we're not sure there is any practical or clinical significance to this finding (100 percent UHMP, 95.2 percent control, significant at .026). Twenty-two of the 25 UHMP practices reported policies that allow patients to contact the practice directly for renewal requests (i.e., they did not require that patients request renewals via the dispensing pharmacy). This finding was not statistically significant (88 percent UHMP, 95.2 percent control, not significant), but is of some practical interest in that it suggests that e-prescribing practices may be more likely to intentionally steer externally originating renewal requests towards the pharmacy.

How renewal requests are received differed considerably for the UHMP and control practices. Importantly, as shown in Table 40 below, the UHMP practices reported that, on average, 40.8 percent of renewal requests originating from community pharmacy came in by phone, 27.9 percent by fax, and 31.0 percent via an electronic request directly into the e-prescribing software, compared with 59.6 percent by phone, 39.1 percent by fax, and 0 percent by e-prescribing at the control practices.

Table 40: How Prescription Renewal Requests are Received

How Prescription Renewal Requests are Received from Community Pharmacies						
Type of						
	Prescription					
	System					
	UHMP	Control				
	Practices	Practices	Significance			
Mean percent community pharmacy requests						
received by phone	40.8%	59.6%	0.274			
Mean percent community pharmacy requests						
received by fax	27.9%	39.1%	0.620			
Mean percent community pharmacy requests						
received by e-prescribing	31.0%	0.0%	0.000			
Mean percent community pharmacy requests						
received by e-mail	0.0%	0.0%	0.069			
Mean percent community pharmacy requests						
received by US mail	0.2%	1.4%	0.001			

E-prescribing technologies may also affect if the practice utilizes a dedicated prescription voice mailbox to receive renewal requests. While not statistically significant, 60.0 percent of e-prescribing practices reported having a dedicated voice mailbox to receive renewal requests, compared to 33.3 percent of non-e-prescribing practices. Another apparent difference in workflow involves the staff member who is primarily responsible for prescription renewal calls. For the UHMP practices, 65.2 percent reported a Medical Assistant (MA) is responsible for prescription renewal calls and 17.4 percent reported

that the front desk/office manager has this responsibility. This compares to the control group who reported 35.0 percent used a MA for this task and 40.0 percent reported that the front desk / office manager has this responsibility. Similarly, 55.0 percent of UHMP practices reported a Medical Assistant (MA) is responsible to pull incoming pharmacy faxes compared to 37.5 percent of the control group and 40.0 percent of UHMP practices assigned responsibility for faxes to the front desk / office manager compared to 56.3 percent of the control practices. The practical significance of this group of findings is unclear. Site visits and interviews with UHMP practices noted that MAs managed the e-prescribing system on behalf of most physicians. Due to the interaction with e-prescribing application, it is logical that the MA would also have responsibility for renewal phone calls, although implementation of e-prescribing by other practices could have different results.

There were some similarities reported with respect to how renewal requests are internall processed by the UHMP and control practices. For instance, both UHMP and control practices managed faxed renewal requests in a similar manner. The most common methods used to manage faxed requests for prescription renewals were:

- 1. Fax is placed in authorizing doctor's mailbox for later retrieval by MA (38.0 percent UHMP, 30.8 percent control),
- 2. Fax is placed on desk of authoring doctor (29.6 percent UHMP, 35.5 percent control), and
- 3. Other (19.9 percent UHMP, 15.0 percent control).

The process of internally communicating phoned- and faxed-in renewal requests was also similar for UHMP and control practices. The most frequently noted means of internal communication for phoned requests was by written note for 80.5 percent of UHMP vs. 78.2 percent of control practices. For faxed-in requests, the fax itself served as the internal vehicle for communicating the request to the responsible prescriber 91.4 percent of the time for UHMP practices and 98.3 percent of the time for control practices.

However, there were also some striking differences with respect to internal renewal request processing. For instance, UHMP practices reported that the patient's paper medical chart is pulled in order to authorize a prescription refill less often, on average, than the control practices (81.5 percent UHMP, 98.0 percent control, significant at .001). The specific reasons for the medical chart pull are shown in Table 41. The most highly scored (3= most common, 2=2nd less common, 1=3rd less common, 0=all others) items for UHMP were "Need to verify last visit date, Pap smear, BP measurement, etc" (mean score of .96), "Lack of general familiarity with the patient (other than need to check last visit)" (mean score .52) and "The chart will be needed for documentation after authorization anyway" (mean score .52). This contrasts with the control practices who rated "The chart will be needed for documentation after authorization anyway" (mean score 1.19) as the most important reason for the chart pull, followed by "Need to verify last visit date, Pap smear, BP measurement, etc" (mean score of 1.00), and "The nature of the drug(s) being requested (e.g., birth control pills, narcotics)" (mean score of .48).

**Table 41: Reasons to Pull Patient's Medical Chart** 

Reason to Pull Patient's Medical Chart to Authorize Prescription Refill - Mean Score (3= most common, 2=2nd less common, 1=3rd less common, 0=all other)							
Type of							
	Prescription						
	System						
	UHMP	Control					
	Practices	Practices					
Need to verify last visit date, Pap smear, BP measurement, etc	0.96	1.00					
Lack of general familiarity with the patient (other than need							
to check last visit)	0.52	0.33					
Uncertainty about what exactly is being requested	0.20	0.24					
Authorizing physician asked for the chart after initially							
reviewing the request w/o it	0.12	0.14					
The nature of the drug(s) being requested (e.g., birth control							
pills, narcotics)	0.32	0.48					
The chart will be needed for documentation after							
authorization anyway	0.52	1.19					

There were also major differences reported in how the responsible physician communicates authorization or denial responses to renewal requests. For UHMP practices, respondents reported that the "physician initials request, gives to MA, MA sends electronically to pharmacy" 48.9 percent of the time, on average, (compared to 4.8 percent at the control practices, significant at .000). UHMP practices reported that the "Physician sends electronically to pharmacy via e-prescribing application" 19.7 percent of the time (compared to 0 percent for the control group, significant at .000). Control practices, on the other hand, reported that the "Physician initials request, gives to MA, MA calls or faxes pharmacy" 79.0 percent of the time, on average (compared to 24.9 percent for UHMP, not significant). There was less of a difference if the initial renewal request was by fax, with UHMP reporting a combined 70.2 percent for, "Physician initials request, gives to MA, MA calls or faxes pharmacy" or "Physician initials transcribed request, gives to MA, MA calls or faxes to pharmacy," compared to a combined 93.0 percent for the control practices.

Medical record documentation differs due to the e-prescribing technologies available to UHMP. Only 9.6 percent of UHMP practices responded, "Physician writes a note in the chart" (compared to 35.4 percent of the control practices, significant at .000) and 34.4 percent of UHMP practices responded, "MA or other staff writes a note in the chart" (compared to 55.4 percent of the control, not significant). More importantly, for UHPC practices, 25.2 percent responded, "Copy of internal renewal messaging form placed in chart" (compared to 9.2 percent of the control, significant at .003) and another 17.6 responded "Renewal note is printed from e-prescribing application and placed in chart" (compared to 0 percent of the control, significant at .000).

**Table 42: Phoned-in Renewal Requests** 

How Phoned-in Renewal Requests are Documented in Patient's Medical Chart

	Type of Prescription		
	UHMP	Control	
	Practices	Practices	Significance
Physician writes a note in the chart	9.60%	35.40%	0.000
MA or other staff writes a note in the chart	34.40%	55.40%	0.402
Copy of internal renewal messaging form placed in			
chart	25.20%	9.15%	0.003
Renewal note is printed from e-prescribing			
application and placed in chart	17.60%	0.00%	0.000
Other means	13.60%	0.00%	0.000

The overall impact on workflow and effort is summarized by the respondents who were asked to use a 7 point Likert scale to: "Rate the relative resource intensity of managing prescription renewal requests and responses from start to finish for each of the following ways a renewal request is received." UHMP and control practices rated phoned-in requests similarly in terms of resource intensity (5.12 for UHMP practices compared to 5.14 for control practices, significant at .041). However, UHMP practices rated fax requests as much easier in resource use (3.40 for UHMP compared to 4.14 for control practices, significant at .004). Most importantly, the UHMP practices rated requests that arrived by an e-prescribing application as the least resource intensive (2.83 for e-prescribing practices compared to no score for the control group).

**Table 43: Relative Resource Intensity** 

Relative Resource Intensity of Managing Prescription Renewal Requests and Responses from Start to Finish (1 = lowest resource intensity, 7 = most resource intensity)

	Type of		,
	Prescription		
	System		
	UHMP	Control	
	Practices	Practices	Significance
Phone	5.12	5.14	0.041
Fax	3.40	4.14	0.004
e-Prescribing application	2.83	0.000	0.000

Evaluating the processes employed by UHMP practices that utilize e-prescribing compared to a control group of physician offices that used the traditional paper prescribing methods indicates that there is a definite difference in how the practices operate. The study also recorded that the UHMP practices rated the use of resources for e-prescribing applications much less than other methods of managing prescription renewal requests. Determining an actual return on investment may not be practical at this

time, however the UHMP practices that use e-prescribing describe gains in efficiency and accuracy compared to the control practices that do not use the e-prescribing technology.

# **Stage 2: Production Testing of Initial Standards** (RXFILL, Prior Authorization, Medication History)

Prescription Fill Status Notification (RXFILL)

We assessed baseline (pre-test) physician attitudes towards RXFILL / NoFill notification via the Prescriber Survey administered during Stage 1. Relevant results are shown in Table 44 below.

Table 44: Interest in RXFILL and NoFill

	Practice Type			
Question	UHMP (n=50)	Control (n=53)	t-test	Significance (2-tailed)
How interested would you be in being able to determine whether or not a prescription you wrote was ever actually picked up at the pharmacy?	5.78	5.38	1.37	0.17
How interested would you be in being notified when a prescription you wrote was never actually picked up at the pharmacy?	6.18	5.23	3.21	0.00

<sup>1=</sup> not at all interested to 7 = very interested

UHMP Physicians were significantly more interested than control prescribers in being notified about a NoFill event (6.18 on 1-7 scale vs. 5.23, p=0.00). Baseline interest scores among the UHMP respondents were higher for NoFill alerting than for fill notification (6.18 vs. 5.78, not tested for significance), but interest level scores were nonetheless quite high for both.

We conducted a production test of RXFILL transactions at 9 UHMP practices. We also attempted a production test of linked NoFill alerts, though this latter test failed to materialize in a meaningful fashion.

The original go-live date for RXFILL was planned for the 2<sup>nd</sup> week in October. However, it quickly became clear that additional time would be needed to develop training materials and visit with each of the nine practices. Accordingly, go-live was pushed back to October 23<sup>rd</sup> for RXFILL messaging, with the first NoFill alerts expected to begin triggering 10 days later during the first week in November.

Within one week of go-live, a "glitch" was discovered whereby the RXFILL notices coming from SureScripts repository were missing NDC codes. Since these were critical for OnCallData<sup>TM</sup>'s matching logic, the transaction stream was turned off.

The problem was promptly fixed by SureScripts and a second go-live for RXFILL occurred the first week in November, with NoFill alerts expected to begin triggering the 3<sup>rd</sup> week in November. Things appeared to be running smoothly until, in late November,

we were notified by one of the nine RXFILL study group practices that a large number (approximately 50) of NoFill alerts had appeared all at once. These all appeared to be false positive NoFill alerts, and the nine practices were immediately advised to ignore any NoFill alerts and that the feature was going to be temporarily suspended. A quick investigation by InstantDx and SureScripts revealed that RXFILL transactions had been flowing only to OnCallData<sup>TM</sup> prescribers in Rhode Island but not in Ohio, apparently because the Ohio (UHMP) physician DEA numbers had never been loaded into SureScripts' RXFILL triggering system. The absence of RXFILL messages to the UHMP practices resulted in the false positive NoFill alerts.

Neither InstantDx nor SureScripts were able to provide a clear explanation for how this oversight occurred. InstantDx was indeed monitoring RXFILL transactions, but not at the geographic (or individual prescriber) level: monitoring showed that RXFILL transactions were moving (it just wasn't granular enough to reveal that none were moving to the Ohio OnCallData<sup>TM</sup> installation). Neither InstantDx nor SureScripts were aware of the problem until the massive (mis-)firing of (false positive) NoFill alerts. Fortunately, there were no patient care consequences of this mishap, although there certainly could have been.

A third go-live for RXFILL began on December 1<sup>st</sup>, and RXFILL transactions between SureScripts and the 9 test UHMP practices have successfully been moving ever since. Some transaction statistics and limited post-test user interview results are presented below.

As with the first two attempted production tests, it was anticipated that linked NoFill alerting would begin 10 days after go-live (or around December 10<sup>th</sup>). However, periodic informal queries of the 9 test practices throughout December and early January failed to turn up any users that had actually seen a NoFill alert. InstantDx was unable (due to resource availability) to supply the weekly logs of NoFill alerting activity that UHMP had requested. Without this information during the test, we had no way of tracking where NoFill alerts were firing, if at all.

As it turns out, the lead developer at InstantDx made a unilateral decision to disable the NoFill alerting code on or around December 8<sup>th</sup>, shortly before NoFill alerts were anticipated to begin firing. We were not informed of this action until 1/12/07.<sup>20</sup> There was thus *no production test of linked NoFill alerting*.

RXFILL transaction times (performance) were not reported to us. As deployed in this test, these times would be clinically irrelevant, in our estimation, since RXFILL messaging is not real-time (e.g., there is no user triggering the request and waiting for a response; it thus doesn't matter if the transaction takes a fraction of a second or 10 seconds).

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<sup>&</sup>lt;sup>20</sup> The lead developer had to make an emergency trip to India to tend to the sudden illness of a family member (who ultimately died). He had just pulled the NoFill code to perform some final testing / debugging when he had to drop everything on short notice. He decided (probably rightfully so) that it would be most prudent not to deploy the code into production without the additional testing.

We were able to ascertain from the SureScripts data, however, that the lag time from a prescription being time stamped by the pharmacy as having been picked up and the time a RXFILL message for that prescription is generated by SureScripts is, on average, 6.22 days for CVS and 5.92 days for Walgreens. We were unable to ascertain with the data provided whether this (unexpectedly long) delay between the picked-up time and the actual RXFILL messaging time was due to a delay in the pharmacy transmitting picked-up data to SureScripts or to a delay on SureScripts' part after they received picked-up data from the pharmacies, or to a combination of both. Note that Rite Aid-related RXFILL transactions were excluded from the lag-time analysis because Rite Aid provided dispensed data to SureScripts rather than picked-up data (in spite of having committed to the former); thus, RXFILL transaction data provided by SureScripts for Rite Aid filled prescriptions does not include a picked-up time stamp.

It remains unclear as of this writing whether or not SureScripts was generating RXFILL transactions based on initial receipt of dispensed (rather than picked up) data from Rite Aid. We specifically requested that RXFILL transactions *not* be generated based on a dispensed flag, and were assured by SureScripts that all three pharmacies would be providing prescription data with the picked-up rather than the dispensed flag. It is possible that there is an intentional delay in RXFILL transaction generation by SureScripts, specifically because of this Rite Aid situation (e.g., they could be waiting to see if Rite Aid issues a "retraction" to SureScripts for dispensed prescriptions that end up being returned to stock because they were never picked up, which, according to SureScripts, would typically occur within 5 to 7 days; this would not be an issue for CVS or Walgreens since they were not sending prescription data to SureScripts until *after* pick up in the first place).

We remained curious about NoFill rates even though we were unable to measure this directly (since the NoFill alerting function was deactivated). Accordingly, we attempted to match up December NEWRX transaction data from SureScripts for our nine RXFILL test practices with the RXFILL transaction data for these same practices, in order to come up with an estimate for a NoFill rate. However, it has been difficult to reliably match data for this calculation. We have asked SureScripts for additional assistance with this and are awaiting a response. Separately, InstantDx is developing a report that would show a count of new prescription orders sent to CVS, Walgreens and Rite Aid in December for which a matching RXFILL notice was never received. Once in hand, this should provide some insight into NoFill rates for electronically transmitted prescription orders.

As of this writing, the post-test survey (separate instruments for Office Manager and Prescriber) was administered as a structured phone interview by Dr. Elson with the office manager and the (Stage 1) selected physician, separately, for each of the three internal medicine practices that participated in the RXFILL production test. This instrument was created and administered *before* we were informed that NoFill alerting had been turned off during the final production run. Accordingly, Questions 2 through 10 on the Prescriber instrument (with one exception, described in next paragraph) and 2 through 8

on the Office Manager instrument were irrelevant and unnecessary and ended up being skipped when the respondents indicated that they had not seen or were unaware of any NoFill alerts (other than the false positive burst in November).

Interestingly (and inexplicably), one of the interests indicated that she had recently seen (2 days prior to her interview during the 2nd week in January) a single NoFill alert during an e-prescribing session. She was a mixed OnCallData<sup>TM</sup> user type (about 60/40 direct / surrogate), but saw the pointer to the NoFill alert on-screen herself. She simply "ignored" it because it was "very difficult" and "too much work" to respond. The benefit of the NoFill information did "not at all" outweigh the additional work required to respond to it, and she would "definitely not" recommend continuing the NoFill alert function. The other two interests (one predominantly direct- and one exclusively surrogate-based OnCallData<sup>TM</sup> user) had not seen any NoFill alerts and were thus not asked whether or not they would recommend continuing the feature.

By contrast, all three interests felt strongly that the RXFILL function (filled status of a drug accessible via lookup within OnCallData<sup>TM</sup>) should be continued (average 6.5 on a 1 – 7 scale, Question 11 on Prescriber instrument), even though two of the three were unaware that the function existed (until informed by the interviewer), and the third was aware but had neither used it nor was aware of any staff that had.

**Table 45: Interest in Continuing RXFILL by Selected Physician** 

	Number	Yes	No
Were you aware that you could look up (in ONCALLDATA™) the filled status of any prescription sent to CVS, Rite Aid, or		4	
Walgreens during this test?	3	1	2
	Number	Range	Average
Would you recommend continuing this filled status function, even if the NoFill alerts are turned off?	3	6 to 7	6.5
(1 = definitely not to 7 = definitely yes)			

Table 46: Interest in Continuing RXFILL by Practice Manager

	Number	Yes	No
Were you aware that you could look up (in ONCALLDATA™) the filled status of any prescription sent to CVS, Rite Aid, or			
Walgreens during this test?	3	2	1
	Number	Range	Average
Would you recommend continuing this filled status function, even if the NoFill alerts are turned off?	1*	7	7.0
(1 = definitely not to 7 = definitely yes)			

<sup>\*</sup>Due to changes in the survey instrument, this question was only on one of the practice manager surveys.

In the interim, there are some significant lessons learned from the technical preparation for this production test. Problems encountered during the first two attempts to place RXFILL / NoFill Notification into production (missing NDC codes and missing the Ohio DEA numbers in the SureScripts database) were primarily due to the atypical, extremely

aggressive production timeline dictated by the pilot, with limited opportunity for preproduction testing.

While we do not believe that these are problems with the RXFILL standard itself, they did expose the vulnerability of assumption-based, rather than transaction-based, NoFill alerting to false positive alerts. In particular, any breakdown in the arrival of the RXFILL transaction itself or critical data elements within the RXFILL transaction will lead to false positive NoFill alerting. This emphasizes the necessity of the RXFILL / NoFill messaging to occur directly between the pharmacy and the e-prescribing application, perhaps based on a return-to-stock event.

Although the missing NDC codes caused difficulties with matching the original prescription order in OnCallData<sup>TM</sup>'s database with the RXFILL message from SureScripts in this test, the NDC number is not a necessary part of the RXFILL messaging. Instead, if the prescription order number were a required part of the NEWRX standard the order number could be used to match to the RXFILL messages thereby eliminating the need to match on NDC number, patient name, etc. This is not an inoperability problem between the foundation standard and the initial standard because the order number is not a required data element for NEWRX. However, including this information would make RXFILL / NoFill notification function easier.

#### Prior Authorization

The production test began on December 10<sup>th</sup>, 2006, with the first Prior Auth transactions recorded on December 18<sup>th</sup>. Between 12/18/06 and 1/12/07, there were 30 Prior Auth transactions recorded, and these results pertain to those 30 transactions.

As with RXFILL testing, there were some problems with the earliest transactions that were in large part an artifact of the extremely aggressive production timeline (which left little time for working out kinks pre-production). For instance, the first Prior Auth transaction didn't make it through to the RxHub web portal, but the corresponding fax made it thru to the Anthem Prior Auth team in Cincinnati, the fax was processed normally there (but there was no corresponding item found on the RxHub portal when the Anthem Prior Auth team member went to transmit the authorization back). By the time of the 2nd request, the transaction problem had been resolved, but the Anthem prescription plan patient identifier coming through on the fax (and represented in the transaction on the RxHub portal) was not the identifier normally used / recognized in the Prior Auth process, so the Prior Auth team had to do a name lookup. This particular request was further complicated by the fact that the patient in question had dual Anthem eligibility. Although this latter issue wasn't responsible for the identifier problem, it did create a second issue that had to be resolved once the correct patient was identified by Anthem (i.e., which coverage to use).

The identifier issue was a matter of OnCallData<sup>™</sup> including the wrong identifier – pulled from the 271 eligibility responses – in the 278 Prior Auth requests. The transaction implementation guide(s) apparently are ambiguous with respect to which identifier

should be pulled from the 271 response and forwarded in the 278 Prior Auth request, and resolution of this issue required additional communication between Anthem, RxHub, and InstantDx. Nonetheless, by the time of the 3rd transaction, the identifier issue had been corrected on the transaction (i.e., as visible on the form on RxHub's portal), but not on the corresponding fax! Since the fax is used for processing and the portal is only used by Anthem *after* the request has been handled, the Anthem Prior Auth team once again had to do a name lookup. This transaction / fax identifier mismatch issue was merely an application coding oversight (apparently, separate code governed which identifier was included on the transaction and the fax, and only the former was corrected initially with respect to the earlier incorrect identifier issue). This problem was fixed immediately by InstantDx and there were no subsequent incorrect identifier issues or transaction / fax mismatch issues. In addition, the problems encountered with these first three transactions were largely opaque to the UHMP practices that had generated the requests.

Characteristics of these transactions are presented in Tables 47 and 48. The 30 Prior Auth transactions were generated by 17 authorizing prescribers in 13 practices, 7 of which were in the original 18 non-pediatric study group practices and 6 of which were in the extended (for the purposes of the Prior Auth testing) UHMP practice base (Table 47). Twenty-four of the requests came from original study group practices and the remaining 6 came from the extended group. Four of the 17 authorizing prescribers completed and submitted the Prior Auth form electronically within OnCallData<sup>TM</sup> themselves ("direct") for 5 requests; the remaining 25 requests were completed and submitted by surrogates for the other 12 authorizing prescribers. There was at least one Prior Auth transaction for five of the 8 drugs available for electronic Prior Auth processing. There were 11 denials and 19 approvals. *Twelve of the 30 requests turned out to be repeat requests for drugs that had already been either approved or denied* (see mismatches between "Rx Date" and "Auth Date", where latter is *earlier* than the former in Table 47).

Table 47: Prior Auth Transactions, by date requested ("Rx Date") within OnCallData<sup>TM</sup>.

"Auth Date" represents date authorized (approved or denied) by Anthem. Note that Auth Date is earlier in some instances than the Rx Date, indicating that Prior Auth had been requested and processed previously (these instances are marked in the "Repeat" column).

				Prescriber	Direct or	
Rx Date	Auth Date	Repeat	Drug	Code	Surrogate	Status
12/18/2006	12/18/2006		Viagra	Α	Surrogate	APPROVED
12/22/2006	12/22/2006		Celebrex	В	Surrogate	APPROVED
12/22/2006	12/22/2006		Celebrex	С	Surrogate	APPROVED
12/22/2006	12/22/2006		Viagra	D	Surrogate	DENIED
12/27/2006	12/27/2006		Nexium	E	Surrogate	APPROVED
1/2/2007	12/20/2006	Х	Viagra	Α	Surrogate	DENIED
1/2/2007	12/20/2006	Х	Celebrex	С	Surrogate	APPROVED
1/2/2007	12/21/2006	Х	Nexium	F	Surrogate	APPROVED
1/2/2007	12/22/2006	Х	Viagra	G	Direct	DENIED
1/2/2007	12/22/2006	Х	Viagra	Н	Surrogate	DENIED
1/2/2007	12/21/2006	Х	Viagra	I	Surrogate	DENIED
1/2/2007	1/2/2007		Nexium	J	Direct	APPROVED
1/2/2007	1/2/2007		Nexium	J	Direct	APPROVED
1/2/2007	12/19/2006	Х	Nexium	K	Surrogate	DENIED
1/2/2007	12/21/2006	Х	Celebrex	L	Surrogate	DENIED
1/3/2007	1/3/2007		Nexium	M	Surrogate	APPROVED
1/4/2007	12/15/2006	Х	Nexium	С	Surrogate	DENIED
1/5/2007	1/5/2007		Nexium	В	Surrogate	APPROVED
1/5/2007	1/5/2007		Nexium	В	Surrogate	APPROVED
1/8/2007	1/8/2007		Viagra	С	Surrogate	DENIED
1/8/2007	1/8/2007		Nexium	Н	Surrogate	APPROVED
1/8/2007	1/8/2007		Celebrex	N	Surrogate	APPROVED
1/9/2007	1/9/2007		Vytorin	В	Surrogate	APPROVED
1/9/2007	1/9/2007		Lyrica	0	Direct	APPROVED
1/11/2007	1/10/2007	Х	Nexium	Р	Surrogate	APPROVED
1/11/2007	1/9/2007	Х	Nexium	Q	Direct	DENIED
1/12/2007	1/12/2007		Nexium	E	Surrogate	APPROVED
1/12/2007	1/10/2007	х	Vytorin	Р	Surrogate	DENIED
1/12/2007	1/12/2007		Vytorin	Р	Surrogate	APPROVED
1/12/2007	1/12/2007		Vytorin	Р	Surrogate	APPROVED

Using time stamps reported by InstantDx, we were able to calculate the elapsed time from submission of the Prior Auth request electronically from OnCallData<sup>TM</sup> to receipt of the Prior Auth response electronically (from the RxHub portal into OnCallData<sup>TM</sup>) for 26 of the 30 Prior Auth transactions, including 15 (of 19) approvals and all 11 denials (see Table 48).<sup>21</sup> The mean response time for approvals was 140 minutes (2 hrs 20 min) and

<sup>&</sup>lt;sup>21</sup> These turn-around times include actual transaction times for the Prior Auth request from OnCallData<sup>TMTM</sup> to the RxHub portal and the Prior Auth response from the RxHub portal to OnCallData<sup>TMTM</sup>. However, we did not receive time stamps from RxHub, and are thus unable to calculate actual transit times for these transactions. That said, these transit times are "clinically" irrelevant (i.e., given overall request processing time, it hardly matters if the transactions take 20 seconds or 0.2 seconds).

the median was 93 minutes (1 hr 33 min). If the shortest and longest response times are removed (30 min and 931 min, respectively – the latter being an obvious outlier), then the mean response time for approvals drops to 87 min (1 hr 27 min) and the median remains unchanged (93 min). For denials, the mean response time was 730 min (12 hr 10 min) and the median 27 min. However, there was a clear bimodal distribution in the response times for the denials, with 8 of 11 denial responses occurring between 14 and 56 minutes, and the remaining 3 between 2420 and 2916 minutes. Presumably, these latter 3 denials involved a higher level of review, thus accounting for the delay.

Table 48: Response Time (min) for 26 Electronic Prior Auth Requests, by approval status

Response time is the difference between the time a Prior Auth request transaction was sent from OnCallData<sup>TM</sup> (to the RxHub portal) and corresponding response transaction was received back.

Drug	STATUS	Response time (min)
Nexium	APPROVED	30
Celebrex	APPROVED	34
Vytorin	APPROVED	37
Vytorin	APPROVED	38
Nexium	APPROVED	44
Nexium	APPROVED	55
Celebrex	APPROVED	65
Nexium	APPROVED	93
Nexium	APPROVED	98
Nexium	APPROVED	110
Nexium	APPROVED	112
Nexium	APPROVED	129
Vytorin	APPROVED	150
Celebrex	APPROVED	172
Nexium	APPROVED	931
Nexium	DENIED	14
Viagra	DENIED	14
Celebrex	DENIED	15
Viagra	DENIED	21
Viagra	DENIED	26
Viagra	DENIED	27
Viagra	DENIED	42
Viagra	DENIED	56
Vytorin	DENIED	2420
Nexium	DENIED	2482
Nexium	DENIED	2916

Unfortunately, we have no baseline measurements for comparison (e.g., Prior Auth request-to-response turn-around times before implementation of the electronic Prior Auth production test). However, given the nature of the Prior Auth review workflow at Anthem (i.e., entirely fax-based with the exception of the electronic response submission via the RxHub portal), there is no reason to expect that these turn-around times would be any faster with the electronic Prior Auth process that we tested. Indeed, since Anthem

was faxing responses back to the practices *before* logging into the RxHub portal to submit the electronic response, the turn-around times we documented are, if anything, probably *longer* than the baseline turn-around times for manually faxed Prior Auth requests. Instead, any time (and workflow) benefit from the OnCallData<sup>TM</sup>-mediated electronic Prior Auth process would be due to reduced time and effort to: a) learn that a drug has a Prior Auth requirement, which often doesn't occur until the prescription has been sent to the pharmacy and the pharmacist learns of the Prior Auth requirement during pre-adjudication with the PBM; b) locating the phone number, web-site, or paper form needed to make the Prior Auth request, and; c) manually completing the form and faxing (probably less relevant than a and b).

A Prior Auth evaluation interview questionnaire was developed by Dr. Elson (see Appendix G). During the week of 1/15/07, we began contacting users who had submitted Prior Auth requests from within OnCallData<sup>TM</sup> (according to the Prior Auth transaction reports from InstantDx), in order to conduct structured telephone interviews. Seventeen MAs (medical assistants) and 3 physicians were contacted. To date, none of the physicians have agreed to participate in a follow-up interview, but phone interviews were conducted with 9 of the 17 MAs. Results from these 9 interviews are shown in Table 49 below.

**Table 49: Results of Prior Auth Interviews** 

Question	Range	Average
Number of electronic Prior Auth requests received	1 to 6	2.1
How easy/difficult was it to use the electronic Prior Auth feature?     (1 = much harder to 7 = much easier)	4 to 7	6.0
3. How useful did you find the electronic Prior Auth feature to be?  (1 = not at all useful to 7 = very useful)	4 to 7	6.2
How did the electronic Prior Auth request system effect the time required for you to complete the request?     (1 = took much longer to 7 = much faster)	4 to 7	6.0
<ul> <li>9. Would you recommend that UHMP and OnCallData™ continue this electronic Prior Auth function?</li> <li>(1 = definitely not 7 = definitely yes)</li> </ul>	4 to 7	6.4

In general, user perceptions of the electronic Prior Authorization feature within OnCallData<sup>TM</sup> were overwhelmingly positive. Even though we have been unable to conduct interviews with any of the physicians who used this feature directly, indirect reports from the practices involved suggest that they were similarly enthusiastic.

There were also lessons learned from the entire implementation process. These findings were reported to us by RxHub, and presumably represent a synthesis of their experience with *all* of the eRx pilots that tested Prior Auth, not just ours. These findings (or, to use RxHub's expression, "challenges") are listed below:

• Much of the 'interoperability' testing was done through analysis of the forms and implementation

Pilot Testing of Electronic Prescribing Standards

- Implementation of multiple standards is cumbersome (X12, HL7, LOINC & XML)
- Four industry implementation guides in various stages of completeness and usability were involved in the implementation (a problem echoed by InstantDx)
- Same data is required in multiple places (278, 275 and PA Attachment)
- Predefined therapy categories
  - Does not meet requirements of payer forms
  - Does not support unsolicited model well
  - Unable to standardize questions as assumed
- Requirement for conditionality of questions modified and tested conditionality in this pilot
- New requirement for 'check lists'
- Developed additional LOINC codes for custom questions
  - Yes/No, Free Text or Date response
- Most questions are custom questions
- Requirement for comments or additional text

In addition, the RxHub Portal only allowed an "Approve" or "Denied" response and nothing beyond that (i.e. "PA not required" or "Prior approval obtained").

Lastly, the Anthem Prior Auth team felt that the conversion of the Prior Auth questions to the format required for inclusion in the formulary data file was "not an easy task", even for only the 8 drugs involved in our test. The concern was expressed that "once you look at how many [Prior Auth] forms WellPoint has and how often they change, and then multiply by the number of plans, it becomes a massive task."

#### Medication History (RXHREQ, RXHRES)

RxHub's implementation and certification methodology for the RXHREQ and RXHRES is available in the Appendix J. RxHub was prepared to provide us with performance metrics (just for the turnaround time from receipt of a RXHREQ transaction from OnCallData<sup>TM</sup> to the sending of a RXHRES transaction back), but InstantDx asked them not to release that data to us. Instead, InstantDx was going to provide us with these metrics themselves (but, to date, have not).

SureScripts was not contracted to conduct a Medication History test with us and did not provide us with any transaction volume numbers or metrics, although we did ask for them. We thus do not know how many successful RXHREQ / RXHRES transactions occurred between OnCallData<sup>TM</sup> and SureScripts prescription history repository from October through December 2006, what the transaction turnaround time was, nor what the "hit rate" was against SureScripts' MPI. With respect to the latter, we did receive reports from users in early November that they were seeing large volumes of clearly erroneous (e.g., wrong patient) prescription data appearing in the transferred prescription history reports in OnCallData<sup>TM</sup>. Indeed, this may have dampened enthusiasm on the part of some of our test practices for continuing to access and print these reports for the rest of November. A discussion with the development team at OnCallData<sup>TM</sup> pointed to

SureScripts as the source of the erroneous data due to a "bug" that was promptly fixed, and had not occurred since. We were not advised of this issue by InstantDx until early January 2007, nearly 2 months after the fact. At that time, SureScripts only disclosed to us that the problem had something to do with the sensitivity of their MPI matching algorithm, and was resolved after they (presumably) adjusted the sensitivity. We were unable to acquire any additional detail about what we believe represents a highly significant issue.

Table 50 below shows a steady stream of successfully returned non-empty RXHRES transactions<sup>22</sup>. There was an increase in user views from 129 to 488 between September and October, which coincided with training for our Medication History intervention beginning in mid-October. Specifically, we are aware of one large internal medicine practice that began printing transferred prescription history reports at patient encounters immediately following our training visit the 3<sup>rd</sup> week in October. This increased adoption persisted thru November (579 views) but dropped off towards baseline in December (184), which is consistent with our request to continue the test thru November. Even at peak adoption during the test (November), views of available transferred prescription histories only reached ~5%, and dropped down to 1.4% after the test.

Table 50: Medication History Transactions and Views by Users (for all of UHMP),

by month, June thru December 2006

	Medication History Transferred	Medication History Viewed	(%) Percent Viewed	Percent Change from Previous Month
June	12,324	117	0.95	
July	10,447	122	1.17	4.3
August	13,063	134	1.03	9.8
September	9,962	129	1.29	-3.7
October	12,464	488	3.92	278.3
November	11,807	579	4.90	18.6
December	13,295	184	1.38	-68.2
TOTAL	83,362	1,753	2.10	

Follow-up phone interviews revealed that only one of the 9 test practices (the large internal medicine practice mentioned above, an entirely surrogate-based OnCallData<sup>TM</sup> practice) actually followed through with routinely pulling up transferred prescription histories at patient encounters and printing them. An interview with the practice manager at that practice revealed that the MAs at the practice strongly resisted the workflow

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<sup>&</sup>lt;sup>22</sup> We believe that this report from InstantDx just represents RxHub transactions (that was certainly the case through September, since SureScripts prescription history transactions didn't begin until October), but were never able to get confirmation from InstantDx on that issue. If these are all RxHub transactions, the bump from November to December could represent the addition of Anthem lives to RxHub's MPI (Anthem accounts for approximately 13% of UHMP patient volume).

<sup>&</sup>lt;sup>23</sup> Unfortunately, we were never able to get specific user view reports from InstantDx, so we have no electronic audit-based data to confirm where these views were occurring within UHMP

involved (in stark contrast to their rapid embracing of OnCallData<sup>TM</sup> e-prescribing workflow generally), and the physicians for whom the reports were being printed did not find them useful enough to demand that their MAs continue to access and print them. An interview with the physician Medical Director at that practice confirmed the report by the office manager. This physician placed high conceptual value on transferred prescription history both during the baseline site visit interview in September and during the phone interview in January. However, he did not feel that he and his partners had been adequately trained on how to use the OnCallData<sup>TM</sup> reports and the reports were largely ignored.

Phone interviews with the Medical Director internists at each of the other two internal medicine practices in the 9 practice test group revealed somewhat different findings. Neither of these other internal medicine practices sustained any printing of prescription history reports during November. However, both of these internists were direct OnCallData<sup>TM</sup> users and were aware of and had used the transferred prescription history feature even before our test. Both had strong positive feelings about the feature. Results of these three interviews are summarized in Table 51 below.

Table 51: Structured Phone Interviews with 3 Internists Regarding Medication History Test

Prescription History	N	Range	Average
When available, how would you rate the usefulness of these prescription histories, in general?  (1 = not useful to 7 = very useful)	3	6	6.0
When available for you to review, what impact did the prescription histories generally have on time spent during an encounter?  (1 = took more time to 7 = saved time)	3	3 to 6	4.3
When available, was reviewing these prescription histories worth the effort?  (1 = took much longer to 7 = much faster)	3	7	7.0
Would you recommend continuing to print prescription histories for review?  (0 = not applicable, 1 = definitely not 7 = definitely yes)	2	0 to 6	3.0

**Reasons Prescribers Found Printed Prescription Histories Useful** 

Reason	N
Able to look up information that patient could not provide	2
Able to identify drug seeking patients	3
Able to identify compliance issues	3
Help build medication list for new patients	1*
Help update medication lists during visits	1*

<sup>\*</sup>Due to changes in the survey instrument, this question was only on one of the prescriber surveys.

There were also other lessons learned, listed below:

• Strong pos perception of utility but not translated into adoption (awareness, usability / training)

- Something about consent handling
- Something about false-positive matches
- Something about usability, training, workflow and application integration

# Stage 3: Laboratory Testing of Initial Standards (Structured Sig, RxNorm)

### Structured Sig

The sample of 10,000 new prescription messages included 2217 distinct Sig strings, the most common being "take 1 tablet daily" (n=1809) and "take 1 tablet twice daily" (n=474). Of all Sig strings in the sample, 677 were used more than once and 1540 were unique.

Of the 45 fields represented for the mapping exercise, 10 (22%) were not used by any reviewer for any Sig. These unused fields were the "rate of administration" and "rate unit of text" fields from the dose segment, all six of the fields in the dose calculation segment, and "multiple route modifier" and "indication value units." Of the 42 unique Sigs in the mapping sample, one was excluded from the analysis because it had been erroneously assigned to only one reviewer.

Among all 41 Sigs that were mapped, there were no instances in which any two reviewers agreed on the representation across all segments and fields.

Fifteen (35.7%) of the 42 Sigs could be represented by a single set of the Sig fields, without making use of the "repeating Sig" feature in the standard. The remaining 27 Sigs (64%) were represented by at least one reviewer using more than one "repeat" of the Sig fields (which were represented by inserting additional lines for the same Sig in the spreadsheet). Among these "repeating" Sigs, there was wide variation in the number of iterations that the reviewers felt were necessary (see Table 15, last column). All reviewers agreed on the number of required iterations for six of the 27 repeating Sigs (22%). The majority of these "repeating Sigs" (63%) were represented with two or three iterations by all reviewers. The maximum number of iterations that any reviewer used to represent a Sig was six; at least one reviewer used five or six iterations for 7 of the repeating Sigs (26%). For seven (26%) of the repeating Sigs, each of its 3 reviewers had a different opinion regarding the number of repeats required to accurately represent it.

We performed more detailed comparisons of agreement among the 15 Sigs that were represented by all reviewers using a single iteration or line in the database. In analyzing agreement by segment, there were many instances in which two reviewers had populated all fields within a segment using the same values for a given Sig, but there were far fewer instances in which all three reviewers had this level of agreement. Levels of agreement were highest for the "Dose" and "Interval" segments (Table 52). Four segments had no instances of agreement: repeating Sig, duration, dose restriction, and the stop segment. In analyzing agreement at the level of individual fields, there were 14 fields in which at least 2 reviewers had used the same values to represent the same Sig (Table 53). Among the

remaining fields, there were 10 that were not used by any reviewer, and another 19 for which there no instances of agreement between any 2 reviewers among the non-repeating Sigs. (43 - 10 (not used) - 14 (with some agreement) = 19 with no agreement)

Table 52: Levels of Agreement for Individual Segments

(Single-Iteration Sigs, N=15)

<u> </u>			
Segment	Number with All 3 Reviewers in Agreement	Number with 2 Reviewers in Agreement	Number with No Agreement
Repeating Sig	N/A	N/A	15
Dose	3	10	2
Dose Calculation		Not used	
Vehicle Name	1	0	14
Route	0	1	14
Site	0	3	12
Frequency	1	6	8
Administration Timing	0	2	13
Interval	4	7	4
Duration	N/A	N/A	15
Dose Restriction	N/A	N/A	15
Indication	0	2	13
Stop	N/A	N/A	15
Sig FREE TEXT STRING Ind	0	9	6

Table 53: Levels of Agreement for Individual Fields\* (Single-Iteration Sigs, N=15)

Field	Number with All 3 Reviewers in Agreement		Number with No Agreement
Dose Indicator	13		1
Dose Delivery Method Txt	12		2
Dose Delivery Method Mod Txt	0	1	14
Dose	6	7	2
Dose Units Txt	12	1	2
Vehicle Name	1	0	14
Route Txt	0	1	14
Site Txt	0	3	12
Frequency	1	9	5
Admin Timing Text	0	2	13
Interval Value	4	7	4
Interval Value Units Text	8	3	4
Indication Text	0	2	13
Sig FREE TEXT STRING IND	0	9	6

<sup>\*19</sup> fields with no agreement are not shown. Another 10 were left out of the analysis because they were either deleted (rate of administration, rate unit text) or always null (6 fields in dose calculation segment, multiple route modifier, indication value units).

At a qualitative level, it appeared that reviewers were sometimes confused by field names, leading to their consistently interchanging the placement of similar data into alternative fields. For example, no two reviewers mapped the data of any two Sigs into the same fields. Two of four volunteers used the fields Interval Value and Frequency interchangeably. All four volunteers mapped Administration Timing and Indication Timing incorrectly for at least one Sig. One of four volunteers variably placed data in the Interval and Administration Timing fields and one of four volunteers variably placed data in the Frequency and Administration Timing fields. In addition, the Administration Timing field was variably used for Indication Timing, Interval and Frequency. Other fields that consistently caused confusion for all participants were Dose Indicator vs. Dose, Indication Timing Text vs. Indication Text/Indication Value/Indication Value Units, and Indication Timing vs. Site. These segments were universally misunderstood by the volunteers and Sig data was mapped inconsistently and inaccurately by all participants in the mapping exercise.

Some field names were especially confusing to the reviewers and led to incorrect use of those fields, primarily those field names that contained both the words "units" and "text" in the same field name. Reviewers were confused when a term that generally suggests numerical values ("units") and a term that implies words or alpha characters ("text") were combined in the same field name.

When Sigs contained multiple dosing and/or multiple frequencies, such as "1 to 2 tablets" or "every 4 to 6 hours", none of the reviewers correctly identified the proper use of the modifier fields for variable dosing or variable frequency. Also in these cases, the Sig Sequence Position was not utilized as described in the Structured and Codified Sig Format Implementation Guide.

Three of the recommended values suggested for the Free Text String Indicator are sufficiently similar that reviewers were not able to determine proper use. The values causing misuse of this field are "1"—Capture what the prescriber ordered; "2"—Completely from Structured Sig; and "3"—Pure free text. None of the reviewers correctly utilized the values for the Free Text String Indicator field.

#### RxNorm

The RxNorm dataset (lblcode-prodcode, RXCUI, concept) was derived from the December 21<sup>st</sup> release version of RxNorm from UMLS. The SureScripts dataset (lblcode-prodcode, concept) was derived from prescription refill requests sent from pharmacies to physicians. Medications within this dataset were actually dispensed by the pharmacy at some time.

After the merge of this dataset, we identified:

- 13,403 unique NDCs from SureScripts.
- 50,025 unique NDC-RXCUI pairings from RxNorm.
- 8,897 (66.4%) SureScripts concepts had no match with an RXCUI

- Of those non-matches:
  - 4,719 (53%) of the SureScripts concepts had no MTHFDA representation.
  - 4,178 (47%) of the SureScripts concepts did have MTHFDA representation
- 4,506 Surescripts concepts matched with an RxCUI (33.6%)
  - o Of those matches:
    - 1,596 (35.4%) of the matched concepts had no MTHFDA representation.
    - 2,910 (64.6%) of the matched concepts had MTHFDA representation

The quantitative study resulted in the following Contingency Table.

**Table 54: Contingency Table** 

Surescripts Concept is:	A Medication Concept	Not A Medication Concept
In RxNorm	4397	110
Not In RxNorm	8829	68

The quantitative study shows the following results:

**Table 55: Quantitative Results** 

Table 33. Qualitative Results						
Test	Result					
Proportion of Overall Agreement	33.30%					
Proportion of Specific Positive Agreement	49.59%					
Proportion of Specific Negative Agreement	1.48%					
Specificity	0.75%					
Sensitivity	97.56%					
PPV	33.24%					
NPV	37.85%					

The qualitative study resulted in the following reports.

#### Report #1: Brand/Ingredient Mismatching

- 1. Medication Source of the Error: Propoxyphene/APAP 100 mg/650 mg, Hydroxyzine Pamoate, Hydroxyzine Hydrochloride
- 2. The Database Cause of The Error: RxNorm
- 3. Description of the Error: RxNorm incorrectly maps an AB generic propoxyphene/APAP to Wygesic rather than Darvocet. Ingredient mismatch from hydroxyzine pamoate to Atarax, hydroxyzine hydrochloride to Vistaril.
- 4. Analysis of the Error: This problem stems from the granularity of the ingredient concept. In certain cases, the salt form is important to know to distinguish clinical concepts. Also, while one brand (barring reformulation) links with only one generic set of ingredients, an ingredient may link to more than one brand (e.g. Tylenol links specifically to acetaminophen, but not vice-versa).
- 5. Note: This problem has already been addressed with the 12/21 revision. Further specific test will confirm if this is still a problem.

#### Report #2: MTHFDA Table/Legacy Coding

- 1. Medication Source of the Error: Phenobarbital, probably any DESI drug.
- 2. The Database Cause of The Error: RxNorm, MTHFDA
- 3. Description of the Error: RxNorm does not catch many NDCs that are obsolete in the MTHFDA database (may also extend to the VANDF and Multum).
- 4. Analysis of the Error: -Because RxNorm doesn't share the same "history" of using NDCs because only the MTHFDA only contains currently approved products, NDCs that are obsolete due to manufacturing (e.g. Baycol), or reformulated (e.g. Kao-Pectate contains neither kaolin or pectin anymore) have not been integrated into the RxNorm system. While pharmacy systems usually contain obsolete NDC codes due to billing purposes, a system that regularly updates and drops terms that are no longer supported may be a liability when trying to construct a past for a patient. This may become a problem when trying to construct a Medication History.

#### Report #3: Over-The-Counter Drugs

- 1. Medication Source of the Error: ASA, Tylenol, Hydrocortisone, Blue-Emu, etc.
- 2. The Database Cause of The Error: RxNorm
- 3. Description of the Error: RxNorm does not cover OTCs. OTC matches with MTHFDA-matched NDCs This is not surprising, since the source vocabularies are known to be inconsistent and incomplete regarding OTC tracking.
- 4. Analysis of the Error: This is a systemic problem for RxNorm. Because RxNorm is dependent on source vocabularies for content, the question of how to deal with situations where the source vocabularies are mutually deficient has not been addressed yet. Since OTCs are valid medication concepts, they should be scheduled for inclusion in some future version. How this content is included will be a planning issue for future releases of RxNorm, since none of the source vocabularies are expected to become proficient in this area. It is doubtful that "authoritative information" will ever become available for OTCs due to lack of source vocabulary desire to expend resources to create entries that will not be bought (see above for limitations). This is an area where RxNorm could develop unique content separate from the other sources.

## Report #4: The Conceptual Limit of "Medication" – Insulin

- 1. Medication Source of the Error: Insulin (Specifically Humulin and Novolin)
- 2. The Database Cause of The Error: RxNorm
- 3. Description of the Error: Inputting different dosage forms of insulin (pen, injectable, infusion formulation) return as "injectable."
- 4. Analysis of the Error: In this case, although the ingredient and brand are the same, the way that the dosage form is delivered to the patient may be different. RxNorm's design philosophy is designed on how "a clinician may order for a patient or administered" device differences (such as pens and cartridges) would constitute a clinical difference. This is one of the situations where the available granularity is not sufficient to describe clinical reality. These entries may be slated for local editing for situation-specific environments.

## Report #5: Medical Devices

- 1. Medication Source of the Error: Lancets, Strips, Spacers
- 2. The Database Cause of the Error: SureScripts
- 3. Description of the Error: RxNorm inconsistently matches devices with RXCUIs. Spacers seem to have a RXCUI, but diabetic supplies do not.
- 4. Analysis of the Error: Although diabetic and asthma supplies are routinely treated as "medications" in the Medication History, they are not technically medication concepts. This error is not RxNorm's fault. However, this is a situation where RxNorm should determine whether it should allow medication-related devices to be entered into the system, because certain devices are tracked through Medication History.

## Report #6 (ongoing): Concept Validity

- 1. Medication Source of the Error: Levoxyl (Prednisone)
- 2. The Database Cause of the Error: RxNorm
- 3. Description of the Error: There are still some concepts that are matched incorrectly.
- 4. Analysis of the Error: There are still some mismatches in the post-editing process. These errors must be manually caught and corrected.

## Report #7: Bioequivalence

- 1. Medication Source of Error: Any thyroid mediation, Sarafem (fluoxetine)
- 2. The Database Cause of the Error: RxNorm
- 3. Description of the Error: Certain medications, although they share the exact same clinical ingredient name, are not considered bioequivalent concepts to each other and are treated differently clinically.
- 4. Analysis of the Error: No recommendation can be advanced for this problem. Based on how RxNorm is constructed, any brand that shares the same ingredient is linked together. This will be an issue that systems will need to perform local editing to ensure the situation-specific links are performed correctly.

#### Report #8: Dosing intervals

- 1. Medication Source of Error: Fentanyl Patch, Nictotine Patch, Transderm-Scop
- 2. The Database Cause of Error: N/A, but RxNorm may introduce error
- 3. Description of the Error: RxNorm has chosen to display release forms for patches as dose per hour. RxNorm displays Nicotine patches 0.833 mg/hr where the common form of the dose is Nicotine Patches 21 mg/d.
- 4. Analysis of the Error: Patches and other depot dosage forms are designed for mostly qd or longer intervals of dosing. Pharmaceutically speaking, the doses are averages only if the dosage form is consumed for the prescribed amount of time. Although both displays of doses are technically correct, this will lead to confusion of the doses. It is strongly suggested that the synonym vernacular form of twelve, twenty-four, or longer hours is retained for display in clinical systems, as dose conversion adds another area where a prescriber could err.

# Report #9: Extended Dose Nonequivalence

- 1. Medication Source of the Error: Diltiazem (and its release forms), Cipro XR
- 2. The Database Cause of the Error: RxNorm
- 3. Description of the Error: RxNorm over generalizes medications with different release mechanisms such as Cipro XR from standard release Cipro to one RxCUI.
- 4. Analysis of the Error: Careful work must be done to determine where extended release dosage forms exist. In this case, it would be helpful to identify these drugs using SBD rather than SCD, since all dosage forms are not created equal clinically.

#### **Stage 4: Safety and Cost Impact**

#### Medication Error and Adverse Drug Events Analysis

The tables presented below report the total number of ADE hits by UHMP and control group physicians and also look at number of ADE hits pre and post e-prescribing for the UHMP physicians classified as e-prescribers.

Table 56: Adverse Drug Events by Practice Type, All Data Sources Combined

		Total	
All data combined	Number of ADE hits	Encounters OR Rx	% of ADE hits
UHMP eRx	5,343	2,941,920	0.18%*
UHMP eRx - PRE	3,197		0.11%**
UHMP eRx - POST	2,146		0.07%**
UHMP non eRx	1,484	861,938	0.17%
Control Group	1,831	522,249	0.35%*
MD not in any study group	5,648	2,806,099	0.20%
Data could not be assigned to group	4,825	3,238,022	0.15%
TOTAL	19,131	10,370,228	0.18%

<sup>\*</sup>Difference between UHMP eRx and control group physicians is statistically significant (Chi-square=612.8, p<.0001). \*\*Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=2932291.2, p<.0001).

Looking at all data sources combined, it appears that control group physicians (non-eprescribers) had a greater number of ADE hits then the UHMP e-prescribing physicians. 0.37% compared to 0.18%, respectively. The data also show that the UHMP e-prescribing physicians had fewer ADE hits after they began e-prescribing (0.11% pre compared to 0.07% post). Both of these differences were statistically significant.

**Table 57: ADEs by Practice Type, Concept Data** 

	Number of		% of ADE
Concept <sup>TM</sup> Data*	ADE hits	Encounters	hits
UHMP eRx	2,694	1,994,302	0.14%
UHMP eRx - PRE	1,471		0.07%**
UHMP eRx - POST	1,223		0.06%**
UHMP non eRx	1,130	687,976	0.16%
Control Group		0	
MD not in any study group	400	479,078	0.08%
TOTAL	4,224	3,161,356	0.13%

<sup>\*</sup>Concept  $^{TM}$  is the practice management system in use at UHMP. It does not contain data for control group physicians.

<sup>\*\*</sup>Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=1989165.0, p<.0001).

Table 58: ADEs by Practice Type, Aetna Data

		Total	
	Number of	<b>Encounters OR</b>	% of ADE
Aetna Data*	ADE hits	Rx	hits
UHMP eRx	352	149,175	0.24%
UHMP eRx - PRE	201		0.13%**
UHMP eRx - POST	151		0.10%**
UHMP non eRx	43		0.14%
Control Group		0	
MD not in any study group	202	61,476	0.33%
TOTAL	597	242,053	0.25%

<sup>\*</sup>These data did not contain claims for control group physicians.

Table 59: ADEs by Practice Type, Anthem Data

Anthem Data	Number of ADE hits	Total Encounters OR Rx	% of ADE hits
UHMP eRx	692	240,145	0.29%*
UHMP eRx - PRE	464		0.19%**
UHMP eRx - POST	228		0.09%**
UHMP non eRx	235	48,333	0.49%
Control Group	1,359	336,634	0.40%*
MD not in any study group	5,110	2,257,753	0.23%
TOTAL	7,396	2,882,865	0.26%

<sup>\*</sup>Difference between UHMP eRx and control group physicians is statistically significant (Chi-square=52.8, p<.0001).

Table 60: ADEs by Practice Type, Medical Mutual Data

Table 60: ADES by Tractice Type, Medical Mutual Data						
		Total				
	Number of	Encounters	% of ADE			
Medical Mutual of Ohio Data	ADE hits	OR Rx	hits			
UHMP eRx	1,387	342,990	0.40%*			
UHMP eRx - PRE	955		0.28%**			
UHMP eRx - POST	432		0.13%**			
UHMP non eRx	53	63,040	0.08%			
Control Group	433	133,493	0.32%*			
MD not in any study group	17	7,792	0.22%			
Data could not be assigned to group	3,329	1,935,582	0.17%			
TOTAL	5,219	2,482,896	0.21%			

<sup>\*</sup>Difference between UHMP eRx and control group physicians is statistically significant (Chi-square=16.17, p<.0001).

<sup>\*\*</sup>Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=148521.6, p<.0001).

<sup>\*\*</sup>Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=238997.9, p<.0001).

<sup>\*\*</sup>Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=340741.2 p<.0001).

Table 61: ADEs by Practice Type, QualChoice Data

		Total	
	Number of	Encounters	% of ADE
QualChoice Data	ADE hits	OR Rx	hits
UHMP eRx	218	215,308	0.10%*
UHMP eRx - PRE	106		0.05%**
UHMP eRx - POST	112		0.05%**
UHMP non eRx	23	31,187	0.07%
Control Group	39	52,122	0.07%*
Data could not be assigned to group	1,415	1,302,441	0.11%
TOTAL	1,695	1,601,058	0.11%

<sup>\*</sup> Difference between UHMP eRx and control group physicians is not significant (Chi-square=3.05, p=.08). \*\*Difference between UHMP eRx PRE and POST is statistically significant using McNemar's Test (S=214866.2 p<.0001).

The percentage of ADE hits by practice type in the individual data sets (Tables 57 - 61) appeared to be similar. However, using McNemar's test to compare the UHMP eprescribers during the periods before and after e-prescribing, the differences were statistically significant at p <0.0001. This was also true when looking at the ADE rates for the UHMP e-prescribers compared to the control group physicians using Chi-Square test (p <.0001) for each data set with the exception of QualChoice where the difference was not statistically significant (p=0.08)

Access to patient's medical records was not available during the study. Because of this, there is no way to confirm that these ADE hits were indeed true hits and if they were due to a medication error (preventable adverse drug events) or were non-preventable adverse drug events (no error). Due to time constraints, the number of drug pregnancy trigger hits and drug procedure hits were unable to be examined, as originally planned.

The final results were based on the following ADE monitor triggers hits:

**Table 62: Total Adverse Drug Events Monitory Triggers Hits** 

Trigger Type	Trigger Name	ADE or PADE		eRx	eRx	UHMP eRx POST	UHMP non eRx	Controls	in any study	Unable to map to group
2 or More Drugs	Warfarin Toxicity	ADE	3	2	1	1	0	1		0
Drugs/Misc.	Drug/Age	PADE	4,837	2,541	1,662	879	318	1,794	184	. 0
Drugs/Misc.	Drug/Gender	PADE	0	0		0	0	0		0
ICD-9 Code	Seratonin Syndrome	ADE	777	276	103	173	25	5	290	181
ICD-9 Code	Neuroleptic Malignant Syndrome									
		ADE	3	2	1	1				1
ICD-9 Code	Delirium (drug induced)	ADE	30			0		0	28	2
ICD-9 Code	Aspirin Gastritis	ADE	68	2	2	0		0	34	32
ICD-9 Code	Poisoning by agents that affect the CardioVascular system	ADE	70	11	9	2	2	0	33	3 24
ICD-9 Code	Dermatitis due to internal substances	ADE	185	8	3		5	0	160	12
ICD-9 Code	Urticaria Contact	ADE	234		2	1	2	_	111	
ICD-9 Code	Poisoning by psychotropic agents	ADE	481	2	1	1	2	0	360	
ICD-9 Code	Poisoning by analgesics, antipyretics and anti-rheumatics	ADE	260	1	1	0		0	153	
ICD-9 Code	Poisoning by agents that affect blood	ADE	143	15	2	13	1	0	117	10
ICD-9 Code	Poisoning by antibiotics	ADE	19	4		4			3	12
ICD-9 Code	Poisoning by other anti- infectives	ADE	37	2		2			13	3 22
ICD-9 Code	Poisoning by hormones and synthetic substances	ADE	107	2		2	30	0	40	
ICD-9 Code	Poisoning by anticonvulsants and anti-parkinsonian	ADE	48		1	0			33	
ICD-9 Code	Poisoning by sedatives and hypnotics	ADE	75		1	0		0		

	Total # of ADE monitor hits		19,131	5,343	3,197	2,146	1,484	1,831	5,648	4,825
		·	· ·	·				•		
10D-9 0006	Toxic Epidermic Necrolysis	ADE	323	63	39	24	32	1	126	101
ICD-9 Code	Stevens Johnson Syndrome,	ADE	203	20	10	0	3	U	1/4	U
ICD-9 Code	Anaphylactic Shock	ADE	203	26	373 18	200	303	9	1,274	1,556
ICD-9 Code	Reaction, Drug NEC	ADE	3,785	641	373	268	303	9	1,274	1,558
ICD-9 Code	toxicity Zaroxylyn Toxicity	ADE ADE	21	3	1	2			5 0	13 0
ICD-9 Code	Lithium or Lithium Carbonate								_	
ICD-9 Code	Hypoglycemia due to insulin	ADE	8	2	2	0			6	0
ICD-9 Code	Poisoning by drugs primarily acting on smooth and skeletal muscle	ADE	64			0		0	54	10
ICD-9 Code	Poisoning by drugs primarily acting on the skin and mucous membrane	ADE	10	1	1	0			1	8
ICD-9 Code	Poisoning by other drugs and medicinal substances	ADE	695	91	57	34	17	0	248	339
ICD-9 Code	Urticaria due to drug	ADE	6,516	1,642	917	725	743	21	2,060	2,050
ICD-9 Code	Poisoning by drugs primarily affecting the GI system	ADE	10			0			8	2
ICD-9 Code	Poisoning by drugs primarily affecting the ANS	ADE	39			0		0	28	11
ICD-9 Code	Poisoning by central nervous system stimulants	ADE	25			0	1	0	16	8
ICD-9 Code	Poisoning by other central nervous system depressants	ADE	54			0		0	48	6

See Appendix K for additional details on ADE hits.

#### Cost Benefit of Formulary and Generics

Formulary and Generics Compliance

As can be seen, formulary compliance is at or above 90% for all three groups. There were no statistically significant differences.

Table 63: Differences in Formulary Compliance, 3 months of health plan data

Practice Type	eRx Status	Formulary Rx	Total Rx	% Formulary
UHMP	No	6,698	7,442	90.00
UHMP	Yes	32,493	35,924	90.45
Control	No	12,305	13,535	90.91

While the majority (58%) of prescriptions written in OnCallData<sup>TM</sup> are informed by eligibility-based formulary, the rate of formulary compliance is not higher among e-prescribing doctors. This is not surprising in light of the fact that most formulary switches occur when the patient takes the script to the pharmacy. If the pharmacist discovers, during the pre-adjudication process, that the prescribed drug is not on the patient's formulary, the pharmacist advises the patient and typically tells them to contact their physician or contacts the physician's office directly.

Ohio pharmacists are required to substitute generics for brand name drugs, when available, unless the prescriber expressly indicates on the prescription that substitution should not occur or the patient requests the brand name drug. As such, we do not expect e-prescribing to have a significant impact on generic substitution rates. However, we analyzed the data provided by Medical Mutual of Ohio with somewhat surprising results.

Table 64: Differences in Generic Dispensing Rates, 3 months of health plan data

Practice Type	eRx Status	Generic Rx	Total Rx	% Generic
UHMP	No	4,100	7,442	55.09
UHMP	Yes	18,733	35,924	52.15*
Control	No	7,609	13,535	56.22*

<sup>\*</sup>Significant main effects, the mean difference is significant at the .05 level.

The control group physicians had a slightly higher proportion of generic prescriptions (46.2%) compared to the e-prescribing UHMP physicians (52.12%). One Way ANOVA showed significant differences between the three groups on the proportion of drugs that were generic (F=5.72, p=.000). Specifically, the difference between the e-prescribing UHMP (A Yes) and the control group practices was significant (Bonferroni Post Hoc Mean Difference [B-A Yes]=-.08, p=.000). The control group practices had a significantly higher percent of generic drugs than the UHMP e-prescribing practices. Differences between UHMP e-prescribing and non-prescribing practices were not significant. Please note that this data set is only for 3 months.

We also looked at the generic dispensing rate in the data from Wolters Kluwer and found similar results. The data from WK was from January 1, 2004 through September 30,

2006. Looking at the 33 months of data, the generic prescribing rate is about 44% for the UHMP physicians and 50% for the control group (see Table 65). Significant differences were found between the three practice types in their distributions of Brand, Generic, and No-Drug Products (Chi-Square=3974.23, p=.000). The proportion of dispensed generic prescriptions among UHMP physicians increased from 40% in 2004 to 49% in January through September 2006. Similar increases were observed in the control group where the proportion of generic prescriptions increased from 46% in 2004 to 56% in January through September 2006. This is likely due to the fact of the large volume of brand drug that lost their patent protection over this time span.

Table 65: Differences in Generic Dispensing Rates, WK data 1/1/2004 – 9/30/2006

Practice Type	eRx Status	Brand Rx	Generic Rx	Non-Drug Product	% Generic
UHMP	No	43,047	33,952	1,692	43.15
UHMP	Yes	225,432	184,538	6,455	44.31
Control	No	133,901	139,622	4,928	50.14

<sup>\*</sup>Chi-Square significant at the .01 level.

As noted above, unless the physician specifically mandates that a drug be "dispensed as written" or a patient requests the brand name drug, Ohio law requires generic substitution. Looking at the Wolters Kluwer data, UHMP and control group physicians were identical (1%) in terms of the proportion of prescription where the provider did not allow substitution. This number was essentially constant throughout the time period (1/04 through 9/06) and between the practice types. However, some of the difference in generic dispensing rates may be due to the fact that a higher proportion of UHMP physicians' patients requested the brand name drug (6%) compared to only 4% for the control group. These numbers trended downward over time from 8% for the UHMP physicians in 2004 to 4% in the 2006 data. Similarly, the proportion of control group patients requesting the brand name drug fell from 5% in 2004 to 3% in the January through September 2006 data.

Using the 3 months of health plan data (described above), we looked at the proportion of prescriptions that were "single source" meaning that they were for brand name drugs that had no generic equivalent.

Table 66: Single Source Dispensing Rates, 3 months of health plan data

		Single		% Single
Practice Type	eRx Status	Source Rx	Total Rx	Source
UHMP	No	3,000	7,442	40.31
UHMP	Yes	15,564	35,924	43.32
Control	No	5,353	13,535	39.55

<sup>\*</sup> Significant main effects, the mean difference is significant at the .05 level.

As can be a larger proportion of UHMP prescriptions were for single source drugs; 43.3% for the e-prescribing UHMP physicians compared to 39.6% for the control group. One Way ANOVA showed significant differences between the three groups on the proportion of drugs that were single source (F=4.59, p=.011). Specifically, the difference

between the e-prescribing UHMP (A Yes) and the control group practices was significant (Bonferroni Post Hoc Mean Difference [B-A Yes]=-.065, p=.010). The UHMP e-prescribing practices had a significantly higher percent of single source drugs than the control group practices. Differences between UHMP e-prescribing and non-prescribing practices were not significant. This difference was statistically significant and not surprising given the results of the generic analyses. Unfortunately, the Wolters Kluwer data did not contain a flag to Signify whether a drug was single or multi-source.

The fact that a larger proportion of UHMP prescriptions are for single source drugs and more UHMP patients request brand names at the pharmacy may explain some of the cost differences observed between the UHMP and control group physicians (see Cost Analysis Section). It is highly unlikely that these differences are due to e-prescribing, as a larger percentage of patients requested the brand name drugs in 2004, before the majority of UHMP practices were e-prescribing

The brand name verse generic drug analysis resulted in the following data. There are 176, 369 total observations in the data set. Out of the total observations, 8978 are anticholestorimia drugs. The following table shows the total number that were prescribed for each of the six types of anticholestorimia drugs.

Table 67: Count of Brand and Generic Anticholestorimia Drugs

	Brand			Generic					
	Crestor	Lipitor	Lovastatin	Simvastatin	Zocor	Pravastatin	Total		
Eprescribe	636	2539	457	512	634	67	4845		
non-eprescribe	315	2334	496	371	497	120	4133		
Total	951	4873	953	883	1131	187	8978		

Based on this information, the ratios for each drug were calculated. This information is given in the table below. There is very little difference between the e-prescribing and non-e-prescribing practices that dispensed anticholestorimia drugs; however the non-e-prescribing practices dispensed more Lipitor, but less Crestor. After running a t-test to compare the means of the anticholestorimia drugs, there was a significant difference.

Table 68: Ratio of Brand and Generic Anticholestorimia Drugs

	Brai	nd		Gener			
	Crestor	Lipitor	Lovastatin	Simvastatin	Zocor	Pravastatin	Total
Eprescribe	13%	52%	9%	11%	13%	1%	100%
non-eprescribe	8%	56%	12%	9%	12%	3%	100%

Next, the average cost for each of the drugs was calculated, however it varies based on the health plan. The table below shows the average costs for each drug. It is worth noting that the two brand name drugs were less expensive on average than all the generic drugs except Lovastatin.

Table 69: Cost of Brand and Generic Anticholestorimia Drugs

	Bra	nd		Generic				
_	Crestor	Lipitor	Lovastatin	Simvastatin	Zocor	Pravastatin		
Average Cost	\$ 86.68	\$ 96.60	\$ 30.01	\$ 110.65	\$ 143.32	\$ 97.80		

# Cost Analysis

# Cost Differences by Practice Type:

As can be seen, between-group differences were statistically significant. Post hoc tests revealed that, in all the years examined, the control group physicians had significantly lower average prescription claim costs compared to both types of UHMP practices. And, the UHMP e-prescribing practices had significantly lower average cost per prescription claim compared to their non-e-prescribing counterparts. The exception to this was for 2004 to 2006 time period; in this case, the difference between the two types of UHMP practices was NOT significant.

**Table 70: Cost Differences by Practice Type** 

	2	004 <sup>a</sup>	2005 <sup>t</sup>		2006 (JanSep.) <sup>c</sup>		2004-2006 <sup>d</sup>	
Practice Type/eRx Status	N	Ave. Cost	N	Ave. Cost	N	Ave. Cost	N	Ave. Cost
1. UHMP - No	16,621	\$54.09	17,210	\$56.63	8,865	\$60.17	42,696	\$56.33
2. UHMP - Yes	96,608	\$52.67	100,566	\$53.37	51,041	\$56.74	248,215	\$53.79
3. Control	63,210	\$48.09	63,744	\$48.69	32,833	\$50.61	159,787	\$48.85

<sup>&</sup>lt;sup>a</sup>F=543.41, p=.000; Bonferroni Mean Difference (1-2) p=.000, (1-3) p=.000 (2-3) p=.000

The fact that these cost differences existed in 2004, before the majority of UHMP practices began e-prescribing, suggests that difference in average cost between the practice types is not due to e-prescribing. Rather, the difference in cost may be partially explained by the fact that UHMP physicians tend to prescribe more single source drugs and fewer generics, and a larger percentage of UHMP patients request the brand name drug at the pharmacy. See the section on Formulary Compliance and Generics for additional details. Additionally, the only patient data available were gender and age range. As such, adjustments for the illness severity of the patients were not possible using the Wolters Kluwer IHR TM data.

The average prescription cost for each type of practice increased from 2004 to 2006, the increase was the largest among the UHMP non-e-prescribing physicians at \$6.08 (11.2% relative increase) compared to a \$2.52 increase among the control group physicians, which represents only a 5.2% relative increase. The average prescription claim cost per UHMP e-prescribing physician increased by \$4.07 or 7.7% from January 2004 to September 2006.

 $<sup>^{</sup>b}F$ =174.45, p=.000; Bonferroni Mean Difference (1-2) p=.004, (1-3) p=.000 (2-3) p=.000

<sup>°</sup>F=214.62, p=.000; Bonferroni Mean Difference (1-2) p=.000, (1-3) p=.000 (2-3) p=.000

<sup>&</sup>lt;sup>d</sup>F=158.45, p=.000; Bonferroni Mean Difference (1-3) p=.005 (2-3) p=.002

The data were limited to only September 2006 with the idea that e-prescribing was very well established within UHMP by this time. Results were similar. The between-group differences were statistically significant (F=7.59, p<.001). Post hoc tests revealed that control group physicians had significantly lower average prescription costs than both types of UHMP practices. And, that UHMP e-prescribing practices had significantly lower average cost per prescription compared to the non-e-prescribing practices.

Table 71: Cost Difference by Practice Type, September 2006 data only

	Sep	ot. 2006 <sup>a</sup>
Practice Type/eRx Status	N	Ave. Cost
1. UHMP – No	609	\$63.33
2. UHMP – Yes	3,178	\$60.37
3. Control	1,747	\$53.91

 $<sup>^{</sup>a}F=7.59$ , p=.000; Bonferroni Mean Difference (1-2) p=.000, (1-3) p=.000 (2-3) p=.000

# Cost by Practice Type and Specialty:

Data were then examined by physician practice specialty: family medicine, internal medicine, and pediatrics. Summary data are presented below, see Appendix L for details on the statistical analyses.

**Table 72: Cost Differences by Specialty and Year** 

			2004			2005		20	006 (JanSe	p.)		2004 - 2006	
Specialty	Practice Type/eRx Status	N	Ave. Cost	F	N	Ave. Cost	F	N	Ave. Cost	F	N	Ave. Cost	F
Family Medicine	UHMP - No	2,607	\$55.10		3,094	\$51.62		2,056	\$53.51		7,757	\$53.29	
	UHMP - Yes	17,269	\$53.84	16.14**	18,244	\$55.61	21.15**	9,864	\$57.87	12.87**	45,377	\$55.43	42.10**
	Control	16,467	\$51.00		16,819	\$52.24		9,440	\$54.25		42,726	\$52.21	
Internal Medicine	UHMP - No	11,795	\$50.56		11,391	\$53.06		5,323	\$57.54		28,509	\$52.86	
	UHMP - Yes	75,129	\$51.49	142.55**	77,796	\$51.75	166.04**	38,297	\$55.03	128.06**	191,222	\$52.31	427.10**
	Control	45,326	\$46.24		45,113	\$46.26		22,194	\$47.85		112,633	\$46.56	
Pediatrics	UHMP - No	2,219	\$71.67		2,725	\$76.64		1,486	\$78.73		6,430	\$75.41	
	UHMP - Yes	4,210	\$68.87	7.91**	4,526	\$72.13	9.43**	2,880	\$75.47	4.48*	11,616	\$71.78	14.36**
	Control	1,417	\$73.73		1,812	\$76.24		1,119	\$73.04		4,428	\$74.57	

<sup>\*</sup>Statistically Significant at p<.05

<sup>\*\*</sup>Statistically Significant at p<.001

The between-group differences in the average cost per prescription claim were significant in every time period examined. Except for Pediatrics, the control group generally had the lowest average cost per prescription. The fact that the average cost per prescription was highest for Pediatrics is surprising. It is likely due to the fact that the majority of pediatric prescriptions are for acute conditions such as ear infections and strep throat. These prescriptions typically have a 10 to 14 day supply. So, in limiting the drugs to those with only a 30 day supply, we may be calculating the cost of prescriptions for chronic conditions such as asthma and diabetes or for very high cost conditions such as hemophilia. Time did not permit a more thorough examination regarding the cause of the higher average cost among Pediatricians.

#### Family Medicine:

For the 2004 to September 2006 period, significant between-group differences were found in average prescription costs for the three practice types (F=42.10, p<.001). Post hoc tests revealed that UHMP e-prescribing physicians had significantly higher prescription costs than both the UHMP non e-prescribing physicians and the control group (Bonferroni mean differences significant at p<.001). The difference in prescription costs between the two non e-prescribing practice types was not significant. (See Appendix L for details concerning other time periods.)

#### Internal Medicine:

For the 2004 to September 2006 period, significant between-group differences were found in average prescription cost for the three practice types (F=427.10, p<.001). Post hoc tests revealed that control group physicians had significantly lower prescription costs than both UHMP e-prescribing and UHMP non e-prescribing physicians (Bonferroni mean differences significant at p<.001). The difference in prescription costs between UHMP e-prescribing and UHMP non e-prescribing physicians was not significant. (See Appendix L for details concerning other time periods.)

## Pediatrics:

During the 2004 to 2006 period, significant between-group differences were found in average prescription cost for the three practice types (F=14.36, p<.001). Post hoc tests revealed that control group physicians had significantly <u>higher</u> prescription costs that the UHMP e-prescribing physicians. And, UHMP non-e-prescribing physicians had significantly higher prescription cost compared to their e-prescribing counterparts. The difference between UHMP non-e-prescribing physicians and the control group physicians was not significant. (See Appendix L for details concerning other time periods.)

#### Cost by Practice Type and Specialty, September 2006:

Looking at the data by Specialty for September 2006 showed significant between-group differences for the Internal Medicine physicians only (F=5.93, p<.001). Post hoc tests revealed that control group physicians had significantly lower average prescription costs than control group physicians (Bonferroni mean differences significant at p<.001). The between-group differences in average cost between the Family Medicine physicians and the Pediatricians were not significant.

Table 73: Cost Differences by Specialty, September 2006 data only

		S	ept. 2006	
Specialty	Practice Type/eRx Status	N	Ave. Cost	F
Family Medicine	UHMP - No	143	\$63.17	
	UHMP - Yes	634	\$58.66	1.36
	Control	540	\$54.92	
Internal Medicine	UHMP - No	314	¥	<b>5</b> 00*
	UHMP - Yes	2,211	•	5.93^
	Control	1,060	\$49.42	
Pediatrics	UHMP - No	152	\$80.15	
	UHMP - Yes	333	\$79.32	0.18
	Control	147	\$82.60	

<sup>\*</sup>Statistically Significant at p<.001

Cost Differences by Practice Type, Prescriptions for Females 40-64 Years: In an attempt to look at a similar group pf patients, data were limited to only prescription claims for females' age 40 to 64 years old. Again, the data had been previously limited to only those from a retail pharmacy and for a 30-day supply. Results of this analysis are presented below. Significant between-group differences were found in all time periods examined. Post hoc tests revealed that difference between the UHMP physician types was only significant in 2004. And, that the control group physicians had significantly lower average prescription costs compared to either type of UHMP physician group.

Table 74: Cost Differences by Practice Type, Prescriptions for Females 40-64

	2004 <sup>a</sup>		20	2005 <sup>b</sup>		2006 (JanSep.) <sup>c</sup>		2006 <sup>d</sup>
Practice Type/eRx Status	N	Ave. Cost	N	Ave. Cost	N	Ave. Cost	N	Ave. Cost
1. UHMP – No	4,800	\$51.24	5,034	\$53.76	2,365	\$59.21	12,199	\$53.83
2. UHMP – Yes	28,918	\$54.12	29,243	\$54.04	14,814	\$56.51	72,975	\$54.57
3. Control	17,396	\$50.66	17,662	\$50.16	8,482	\$50.80	54,540	\$50.49

<sup>&</sup>lt;sup>a</sup>F=25.39, p=.000; Bonferroni Mean Difference (1-2) p=.001 (2-3) p=.000

<sup>&</sup>lt;sup>b</sup>F=26.93, p=.000; Bonferroni Mean Difference (1-3) p=.001 (2-3) p=.000

<sup>&</sup>lt;sup>c</sup>F=30.96, p=.000; Bonferroni Mean Difference (1-3) p=.000 (2-3) p=.000

<sup>&</sup>lt;sup>d</sup>*F*=74.20, *p*=.000; Bonferroni Mean Difference (1-3) *p*=.00 (2-3) *p*=.002

Cost Differences by Practice Type, Prescriptions for Females 40-64 Years, September 2006: Similar results were found when looking only at prescription claims from September 2006 for this patient population. Between-group differences in average prescription cost for 40 to 64 year old women (F=3.23, p<.05). Post hoc test revealed that the control group physicians had significantly lower (\$53.14) average prescription claim cost compared to the UHMP e-prescribing physicians (\$62.82) (Bonferroni mean differences significant at p<.05). The difference between the two UHMP physician types was not significant.

Table 75: Cost Difference by Practice Type, Prescriptions for Females 40-64, September

2006 data only

	Sept. 2006 <sup>a</sup>			
Practice Type/eRx Status	N	Ave. Cost		
1. UHMP - No	147	\$60.59		
2. UHMP - Yes	962	\$62.82		
3. Control	513	\$53.14		

<sup>a</sup>F=3.23, p=.040; Bonferroni Mean Difference (2-3) p=.034

As previously mentioned, the only patient characteristics available were gender and age range. There were no diagnoses codes so we could not adjust for the illness severity level of the patients. Additionally, there was not a unique patient identifier so we could not calculate such metrics as the number of prescriptions written per patient. Similarly, it is conceivable that a single patient may have seen a UHMP e-prescribing physician, a non-e-prescribing physician and even a control group physician throughout the time period of the data. Without a unique patient identifier we could not isolate or exclude patients like these from the analysis. Another limitation of the data was that we were not able to identify whether a prescription claims was on or off-formulary. While the physician groups appeared identical regarding formulary compliance in three months of health plan data, we were unable to verify if this held in the much larger IHR <sup>TM</sup> data repository. The analyses presented above did not control for health plan differences. Health plans may have the most direct impact on prescription cost as the dispensed ingredient cost is equal to the average wholesale price less their negotiated discount. These negotiated discounts vary from health insurance plan to plan and can even vary between employer groups within a single health plan. Lastly, classification as e-prescribing or noneprescribing was essentially arbitrary. While the criterion was set at 150 or more electronic prescriptions in a single month, we may have classified an interest who writes 600 to 800 prescriptions a month as e-prescribing when only a quarter of their prescriptions were sent electronically.

#### Drug Utilization Review

It appears that the e-prescribing UHMP physicians have the lowest rate of DUR edits per 1,000 prescription claims (2.68). The rate was highest among control group physicians at 3.89 per 1,000. As can be seen the number of high dose interactions is more than double the number of drug / drug interactions. OnCallData<sup>TM</sup>, the e-prescribing software used by UHMP physicians, does check for drug / allergy and drug / drug interactions but does nothing to prevent over dose.

Since the data were for only three months, it is impossible to tell if electronic prescribing via  $OnCallData^{TM}$  made a difference on the rates of drug / drug interaction edits overtime. This area warrants additional study.

Table 76: Drug-Drug and High Dose DUR Edits by Practice Type

Practice					DUR Rate/1,000
Type/eRx Status	Drug-Drug	High Dose	Total DUR	Total Rxs	•
UHMP - No	4	29	33	10,874	3.03
UHMP - Yes	54	121	175	65,357	2.68
Control	13	22	35	8,991	3.89
TOTAL	71	172	243	85,222	2.85

Table 77: Drug-Drug and High Dose DUR Edits by Practice Type and Specialty

Table 77: Drug-Drug and High Dose DUR Edits by Practice Type and Specialty										
Specialty	Practice Type/eRx Status	Drug-Drug	High Dose	Total DUR	Total Rxs	DUR Rate/1,000 Rx				
Family Medicine	UHMP - No	0	4	4	606	6.60				
-	UHMP - Yes	5	13	18	7,331	2.46				
	Control	10	5	15	5,001	3.00				
	Subtotal	15	22	37	12,938	2.86				
Internal Medicine	UHMP - No	4	17	21	8,962	2.34				
	UHMP - Yes	49			55,886					
	Control	2	12	14						
	Subtotal	55	121	176	68,271	2.58				
Pediatrics	UHMP - No	0	8	8	1,306	6.13				
	UHMP - Yes	0	16	16	2,140	7.48				
	Control	1	5	6	567	10.58				
	Subtotal	1	29	30	4,013	7.48				
	TOTAL	71	172	243	85,222	2.85				

Though the results by specialty are more varied, UHMP e-prescribing physicians generally have the lowest rate of DUR alerts per 1,000 prescription claims. Overall rates among family practitioners and internists seem quite similar. The rate among Pediatricians is almost three times that of the other specialties. Again, the number of high dose edits far exceeds the number of edits for drug / drug interactions.

#### **Conclusions and Recommendations**

# **Stage 1: Site Visits**

# Adoption of E-Prescribing

Since the adopter and non-adopter practices were matched for this study, the data regarding differences in those practices must be viewed with caution. Adopters have cultures that are more oriented to information, are more cohesive, have a group vs. a "me" orientation, and are more adaptive. We do not know if these existed before they adopted e-prescribing. However, these data point to important factors to consider when recruiting practices to adopt electronic information systems.

The data regarding use rates once the technology was adopted is more informative but that analysis is constrained by the small sample size. Only 25 practices have adopted the eprescribing and they had about 100 physicians that were potential users. At the practice level, two structural variables were found to influence use rates. Pediatric practices have much higher use rates than other primary care practices and internal medicine practices have the lowest rates. We do not know if these factors would influence who would adopt these technologies but once the practice decides to adopt the use rate appears to be higher in pediatrics and family practice groups. The second practice variable that influences overall use rate is physician profiling practices that have physician profiling programs have higher use rates. This probably results from a heightened focus on clinical performance in these practices that carry over to eprescribing use once the technology is adopted. The practice culture also influences eprescribing use after adoption although they differ from those influencing adoption. Use rates are higher in cultures that emphasize quality of care and in practices with cultures that value physician autonomy. For some unknown reason, information cultures have lower use rates possibly because the e-prescribing technology is not used extensively for information purposes. The autonomy cultural trait is often equated to professionalism and individual physician performance. This could explain why it has a negative effect on adoption but a positive influence on use after adoption as the physicians find that it helps them clinically. We caution, however, that these findings are based on a very small sample and might change with a larger study that includes more practices and physicians.

The analysis of e-prescribing use rates at the physician level in the 25 practices presents some very important findings. Physicians in practices with cultures that emphasize quality of care, autonomy and a business orientation have higher use rates. This supports the contention that physicians tend to use technologies more extensively if it fits their professional and business cultures and that e-prescribing fall into this category. Two other factors appear to influence physician level use rates. Women physicians tend to have higher use rates (although not consistently in all of our analysis) and again a high level of trust in the practice organization has a negative influence on use rates. As discussed above, practices with high trust cultures might also be those that do not pressure their physicians to use e-prescribing even though the responded to their owners by adopting the technology.

While the findings from this study are mixed, the analysis provides important information that can be used by payers and practice managers to improve the adoption and use of information technologies. Again, we caution that the findings are based on a very small sample and should be considered in that light. Nonetheless, the findings were analyzed from several perspectives and point the way for more extensive research.

## **Workflow Efficiency**

There is a significant difference between renewal workflow at e-prescribing and non-e-prescribing practices. The main reason for this difference is the additional technology presented in the e-prescribing application. Communications with pharmacies differ between the two types of groups because the e-prescribing practices often rely on OnCallData<sup>TM</sup> to send and receive messages from the pharmacies. OnCallData<sup>TM</sup> is the preferred method for e-prescribing practices to send messages to the pharmacies. There is also a substantial difference in who handles the renewal faxes and calls when they come in from the pharmacies. In the non-e-prescribing practices rely more heavily on front desk personnel, while e-prescribing practices often rely on Medical Assistants to process renewal requests. The overall impact on workflow and effort is summarized by the fact that e-prescribing practices perceive using OnCallData<sup>TM</sup> easier than processing a renewal request via the phone or fax.

Evaluating the processes employed by e-prescribing practices compared to a control group of physician offices that used the traditional paper prescribing methods indicates that there is a definite difference in how the practice operates. The study also recorded that practices that use e-prescribing rated the use of resources much less than other methods. Determining an actual return on investment may not be practical, at this time, however practices that use e-prescribing describe gains in efficiency and accuracy compared to practices that do not use the technology.

#### Phone and Fax Tally Sheet Analysis

The results from this section strongly suggest that the time office staff spends on the phone or responding to faxes is decreased when using e-prescribing. The only recommendation is in regards to the increased volume of phone calls received by practices from patients with complaints that their e-prescription was never sent / received by the pharmacy. We believe this often occurs because of the lack of education of the staff at the pharmacy, and additional pharmacy education might be necessary to reduce these types of phone calls.

# Stage 2: Production Testing of Initial Standards (RXFILL, Prior Authorization, Medication History)

#### <u>Prescription Fill Status Notification (RXFILL)</u>

RXFILL transactions were successfully tested in a production setting, albeit the messages were not generated by pharmacy systems directly. Instead, the messages were generated indirectly – by SureScripts – after the transfer of prescription data to SureScripts' prescription history repository by participating pharmacies.

The requirement of an intermediating entity (other than merely a transaction routing / certifying entity) created an additional moving part for RXFILL that may have directly contributed to both initial failed attempts to put RXFILL into production at our practices. In the first instance, a critical data element (NDC code of the dispensed drug) was inadvertently omitted from the RXFILL transactions by SureScripts; in the second, SureScripts failed to capture the names of the providers participating in the Ohio test. Under normal pre-production testing circumstances, both of these problems would likely have been detected before RXFILL was moved into production. These two problems thus have no relevance to the RXFILL standard itself. Nonetheless, our experience suggests that using a prescription repository as an intermediating entity in RXFILL transaction generation creates additional potential failure points for RXFILL transactions and highlights the need for especially vigilant transaction testing / certification between trading partners.

With or without this intermediating repository, we found a significant lack of interoperability between NEWRX and RXFILL, largely in the form of a missed opportunity to use an originating order number (beginning with the NEWRX generated by the e-prescribing application) for loop closure when that e-prescribing application receives the corresponding RXFILL notice for that original prescription some hours or days later. Such originating order numbers are routinely used for loop closure in laboratory test ordering and resulting back to the ordering system.

A unique prescription order number is always created by the e-prescribing vendor, but it remains an optional component in NEWRX and does not exist at all in RXFILL (see Sec 6.4.8, p 29 of NCPDP Pilot Guidance Document). Of course, this should not be a *required* field in RXFILL, since RXFILL must be able to handle prescriptions *not* originating from an e-prescribing application in the first place (e.g., hand-written prescription or prescription printed from a computer and hand-carried to the pharmacy).

The intermediating repository complicates this issue further in that it creates yet another interoperability point that resides in between NEWRX and RXFILL. It is unclear to us what messaging standard is being used by pharmacies to transmit prescription data to SureScripts' repository, but it is likely a SureScripts' proprietary standard (we are waiting for confirmation that this is indeed the case). In order for an originating prescription number to be included in the final leg of the loop (i.e., RXFILL), it would need to first be transmitted from the pharmacy to SureScripts via whatever messaging format is being used. We are awaiting clarification from SureScripts regarding whether or not this format can carry an originating prescription number.<sup>24</sup>

Another complication accentuated by (but not necessarily exclusive to) the intermediating repository is the issue of the **RXFILL trigger: dispensed vs. picked-up**. Clearly (to us, at least), the clinical purpose of a RXFILL message is to let a prescriber know whether or not a prescription has been *picked up*, not whether or not the prescription was *dispensed to a shelf* to

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<sup>&</sup>lt;sup>24</sup> On a related note, RXHRES optionally ought to be able to communicate an originating prescription order number: if the requesting entity that receives prescription history data via RXHRES happens to be the same entity where some of that prescription data originated, then that entity could use that data for fill matching even in the absence of specific RXFILL messaging. However, this suggests the need for a companion "prescribing software entity" ID.

await pickup. According to SureScripts' implementation practices, pharmacies can only send prescription data to SureScripts' repository either when the prescription is dispensed or when it is picked up, but not both. If the data is sent as dispensed data, but ultimately is returned to stock (i.e., never got picked up), the pharmacy can send a retraction for that prescription to remove it from SureScripts' repository.

For our test, we were expecting that all three participating pharmacies – CVS, Walgreens and Rite Aid – would be sending prescription data to SureScripts' repository only when picked up, and that RXFILL messages would only be generated by data received with a picked-up flag. However, we only recently learned (2<sup>nd</sup> week in January) that one of the three pharmacies – Rite Aid – was sending dispensed data instead of picked-up data to SureScripts' repository. It is quite possible that SureScripts was transmitting RXFILL messages to OnCallData<sup>TM</sup> for these Rite Aid prescriptions (we are waiting for clarification from SureScripts on this). If that's the case, then OnCallData<sup>TM</sup> would have assigned picked-up status to Rite Aid prescriptions for which that status was not yet actually confirmed. Moreover, if Rite Aid issued retractions to SureScripts for some of those prescriptions (which, presumably, did occur for some fraction), we are unaware of any companion "RXFILL retraction" transaction by which SureScripts would have notified OnCallData<sup>TM</sup> of the corrected status. Besides, even if such a retraction transaction did exist on the RXFILL side, OnCallData<sup>TM</sup> would still have been presenting erroneous information to any clinician looking up the fill status of those prescriptions in the interim.

Interestingly, we did find an unexpected 6 day lag time, on average, between picked-up date and RXFILL transaction date for RXFILL transactions related to CVS and Walgreens prescriptions (for which picked-up time stamps were available, unlike Rite Aid-related RXFILL messages, which only had dispensed date). It is possible that this delay was intentional on SureScripts' part (i.e., wait 5 days after receipt of prescription data – whether it has picked-up or dispensed flag – to give time for retractions to percolate before generating RXFILL messages).

Prescribers appear to remain quite interested in having fill status (whether the result of RXFILL or RXHRES) available for lookup, even when they have never done this.

We were unable to successfully complete a production test of NoFill alerting. These NoFill alerts would have been based on application logic linked to SureScripts' repository-triggered RXFILL messages (rather than on true NoFill transactions generated by return-to-stock events at pharmacies). Nonetheless, we gained significant insight into NoFill alerting and related workflow, and would strongly recommend against NoFill alerting without considerable additional testing. In particular, we found that:

- Presumptive (logic-based) NoFill alerting is error prone and could be considered "an
  accident waiting to happen": any disruption of RXFILL traffic will produce a wave of
  false-positive NoFill alerts
- Workflow related to responding to NoFill alerts is remarkably complex and cumbersome, particularly in surrogate-based e-prescribing environments
- Concern about legal liability related to handling of NoFill alerts is quite real; any NoFill alerting implementation should be preceded by a thorough risk management review, the

- development of clear practice policies, and the creation of workflow tools (e.g., response option selection forms, patient communication templates) to implement those policies
- Enthusiasm by prescribers for NoFill alerting was high in principle, but waned once the workflow and liability realities became more clear

#### **Prior Authorization**

The most important findings from our production Prior Auth test were:

- 1. Electronic Prior Authorization is highly dependent on eligibility checking (270/271) and Prior Auth-enabled formulary file transfer (for the unsolicited model tested in this pilot, Prior Auth-enablement included Prior Auth flags AND drug-specific Prior Auth questions; for the solicited model not tested here only Prior Auth flags would be required); attempts by RxHub to use predefined therapy categories and standardized questions to be loaded into the formulary file were deemed insufficient to meet the needs of individual payer Prior Auth requirements, and custom questions had to be used.
- 2. There is ambiguity regarding which plan identifier should be pulled from a 271 eligibility response and included in the 278 Prior Auth request transaction. While this represents a key interoperability finding between eligibility and Prior Auth, it is not clear that modification to standard specifications would be able to correct this (given the multitude and variation of identifiers used by different prescription benefit plans); instead, this issue will likely need to be addressed in the relevant implementation guides and carefully tested during certification between each e-prescribing vendor and prescription benefit plan Prior Auth transaction partner.
- 3. Twelve out of 30 (40%) of the Prior Auth requests originating from OnCallData™ were for drugs that had previously been requested, processed, and approved or denied by Anthem, anywhere from one day to three weeks earlier. This highlights the fact that eligibility checking coupled with a previously transferred Prior Auth-enabled formulary file is insufficient to inform an e-prescribing application of any existing Prior Auth approval or denial status; instead, the e-prescribing application can only be aware that a drug *generally* has a Prior Auth requirement for that plan. We are not in a position to propose a solution to this problem, but it clearly needs to be addressed.
- 4. As expected, electronic Prior Authorization was extremely well-received by prescriber surrogates, the primary users of this feature in our study setting. The perceived benefit (to users) is likely related to how users find out that a drug has a Prior Auth requirement in the first place, how they locate the source of additional information about the requirement and who to process it with, and, in general, other work involved in prepping a request for manual submission. As implemented in this pilot, there was not likely any improvement in turn-around time once a request was submitted (and, in general, this turn-around time was quite short). In other words, any time savings related to Prior Auth processing probably occur at the stage between drug selection by the prescriber (or surrogate) and submission of the relevant Prior Auth form (usually by fax), and we did not specifically measure this interval.
- 5. As designed by InstantDx, the feature required remarkably little training to use. In stark contrast with NoFill notification and Medication History, our findings support the notion

- that electronic Prior Auth would be rapidly adopted with minimal prompting and training if made available.
- 6. Eligibility checking coupled with an unsolicited-model-Prior Auth-enabled formulary file led to extremely well-received Prior Auth functionality at the e-prescribing application level. When combined with faxing, actual Prior Auth transactions were relatively irrelevant in this setting. Indeed, both UHMP and Anthem will likely decide to continue the OnCallData<sup>TM</sup>-mediated, fax-based Prior Auth processing after the RxHub portal comes down and the electronic Prior Auth requests and responses cease. This may be good news in that robust Prior Auth functionality (bringing Prior Auth status and drugspecific questions into an e-prescribing application and allowing responding to those questions and submission of the Prior Auth request from within the e-prescribing application) can potentially be delivered "en masse" without having to wait for application vendors and PBMs to Prior Auth-transaction-enable their systems.

# Medication History (RXHREQ, RXHRES)

Our most significant findings with respect to Medication History are listed below:

- 1. RXHREQ / RXHRES is a mature, stable transaction that interoperates well with a prior X12 271 transaction, at least as implemented by RxHub. Patient identity matching, however, remains a major concern with any MPI matching algorithms that rely on a cluster on non-unique patient identifiers (name, DOB, zip code). This clearly caused some matching issues with respect to patient identification by SureScripts, although we were not provided with full detail about these and they appear to have been resolved. Any patient matching issues around RXHREQ transactions with RxHub would have been resolved at the X12 270 stage, and we did not undertake any formal analysis to detect mismatches there.
- 2. Successful technical execution of RXHREQ / RXHRES does not automatically translate into successful adoption of the resulting transferred prescription history reports by users. Training and workflow issues must be addressed in order to help achieve adoption (which our test failed to do). This appeared to be more of a problem in surrogate-based UHMP e-prescribing practices than in those practices where physicians used OnCallData<sup>TM</sup> directly (though we never received adequate reporting from InstantDx to prove that). Attention also needs to be paid to optimizing the display of transferred prescription history, including reconciling partially overlapping data streams from multiple prescription history sources. Lastly, application functionality around transferred prescription history should include features that expedite integration of transferred prescription history into existing medication list structures within the application.
- 3. In the project's experience, patient consent issues for transferring prescription history from RxHub were not adequately addressed by either the e-prescribing vendor or the user organization (UHMP)

# Stage 3: Laboratory Testing of Initial Standards (Structured Sig, RxNorm)

# Structured Sig

This study shows that the current state of the Sig format does not provide sufficient clarity to lead different operators to map Sigs accurately or consistently. Overall, the low agreement we found among attempts to represent the same prescription information suggests that the Sig standard is unlikely to be ready for adoption as a requirement for electronic prescribing in 2008.

Some of the specific difficulties that we encountered in this pilot attempt at using the standard might be addressed through specific recommendations. We recommend that more examples be added to the Sig format Implementation Guide to show what types of data are intended to be mapped into each field. In addition, correct or further explanations of the apparent inconsistencies in field definitions and examples are needed in the Guide. For example, the Implementation Guide suggests the word "every" in a Sig that contains "every x hours" should be mapped to the Frequency field whereas, intuitively, it would seem the word "every" should be mapped to the Frequency Units Text field. Additional research is needed to identify all instances where confusion over field names and uses leads to misinterpretation of the prescriber's instructions, which in turn could lead to drug therapy mismanagement and jeopardize patient safety.

Simplify field names containing both the words "units" and "text." Examples that caused the most confusion for the Sig mapping reviewers were Dose Units Text (we recommend renaming the field to Dose Text), Frequency Units Text (we recommend renaming the field to Frequency Text), Interval Value Units Text (rename to Interval Value Text), Dose Maximum Value Units Text and Dose Maximum Variable "Units" Text (rename to Dose Maximum Value Text and Dose Maximum Variable Text).

Provide additional definition and examples to clarify the intent and use of the Indication Segment and how its application is different from the Administration Timing, Frequency, and Interval segments.

Clarify use of the Free Text String Indicator and provide examples in the Implementation Guide to avoid misinterpretation of the prescriber's instructions to the patient.

In summary, the Structured and Codified Sig format needs additional work with reference to field definitions and examples, field naming conventions and clarifications of field use where new codes are recommended, such as the Sig Free Text Indicator field. Such research will improve adoption of electronic prescribing, in general, and use of the Structured and Codified Sig format, specifically. It is imperative that the exact prescriber's instructions for medication use be translated into e-prescribing and pharmacy practice management systems to realize the full value of these technologies in reducing medication errors, decreasing healthcare costs and improving patient safety.

#### RxNorm

The number of mismatches currently makes RxNorm unusable as an intermediary to link various vocabularies through the use of one of the common concepts, the NDC number. Work needs to be done in strengthening the linking tables between the shared concepts of RxNorm and pharmacy systems, investigating alternate routes of linking concepts, and the consideration of a process to add unique vocabulary of the RxNorm. None of the recommendations for improvement should detract from the observation that RxNorm is probably the closest to achieving the goal of a standardized medication nomenclature.

Although quantitatively, the match rate was abysmal, this is more due to systemic issues than random issues. This is good news, since systemic issues can be addressed at the macro rather than the micro level. Further work needs to be done with refining the mapping process and considering whether there are other valid source vocabularies to add to the controlled vocabulary.

#### Study Limitations

- 1. The RxNorm RXNSAT Dataset is Incomplete: The RXNSAT portion of the dataset contains all of the concepts that map to RxNorm's RXCUI, including NDCs. There are many NDCs from the SureScripts dataset that do not match with the RxNorm dataset, yet, match using the RxNav system online. Whether this is due to intermediate matching (i.e. NDCs are matched with another concept prior to being matched with RxNorm) or an incomplete dataset is yet to be determined.
- 2. Surescripts Handles Standard Community Prescriptions: Surescripts is designed optimally to capture routine aspects of e-prescribing. This means standard dosage forms, quantities, and a limited pharmacopeia (mostly to oral dosage forms). Injectables, homehealth, and compounded prescriptions are not well represented in this dataset. A future study would entail a deliberate pull of prescriptions from one of those three areas with RxNorm.
- 3. Package Sizes: One of the assumptions made in the study was that there is no difference between package sizes of a drug. Normally, this is the case (Lipitor 10mg 30 capsules is used the same way clinically as Lipitor 10mg 60 capsules). However, there are some cases where the package size matters (KCl 10 MEq 1 mL for dialysis, and KCl 10 MEq in NS 100mL). Most relevant issues that pertain to package size deal with infusions and conceivably with certain extended release formulations. Testing a wildcard variable for package size may be relevant in the future to see if RxNorm differentiates between the clinical presentation of certain drugs (whether KCl arrives to the patient as a syringe for the dialysis machine or an IV bag for slow infusion).

#### Lessons Learned

- 1. Keep RxNorm open to concept revisions post-hoc:
- 2. Consider developing content in areas where the source vocabularies have not: In this study, many of the nonmatches were due to OTCs. These medications are valid concepts and are not covered well by any of RxNorm's source vocabularies. I would hypothesize that injectables, IVs, radiopharmaceuticals, and compounded prescriptions may have coverage problems from the source vocabularies.

- 3. Do Not Rely Upon One Source of Mapping: From this study, it is clear that NDCs do not fully account for medication concepts within RxNorm. Although a perfect matching strategy has not been found yet, please refer to the RAND study for a study that used other mapping sources outside NDC.
- 4. Ingredient Granularity: When performing a concept search, using brand name will map to the correct concepts. However, when using generic name, NDC, or ingredient name, RxNorm tends to not match with precise granularity. For most medications, this does not make a clinical difference, but for certain medications (e.g. warfarin and thyroids), the granularity may become a problem as there may be a match with more synonyms than desired.
- 5. Consider Custom Modifications: A controlled vocabulary should not have a "Not Elsewhere Classified" category, but that does not mean vendors should accept the RxNorm vocabulary as is. Rather, building upon the vocabulary could be a value-added exercise. Some of the systemic problems identified may be better resolved on a customized basis rather than a generalized solution.
- 6. Extended Release Dosage Forms: Many extended release formulations of drugs that are not bioequivalent are considered synonymous within RxNorm. This is due to the schema which RxNorm follows. At this time, it is recommended that a specialized vocabulary be created specifically to address that issue unless RxNorm builds further differentiation into its schema for alternate release forms.

# **Stage 4: Safety and Cost Impact**

### Medication Error and Adverse Drug Events Analysis

From the analyses presented above, it appears that e-prescribing has a positive impact on patient safety in that it lowers the proportion of adverse drug events when looking at certain drug / age and ICD 9 code triggers. We found no instances of a drug / gender adverse drug event. Please note that the vast majority of ADE hits (74.7% or 14,291 out of 19,131) were triggered by a specific ICD 9 code. And, as mentioned previously, we were not able to access patient charts to investigate whether or not real error was involved.

The fact that a significant impact on adverse drug events was found was surprising given that OnCallData<sup>TM</sup> only checks for drug / allergy combinations and drug / drug interactions. We were unable to get reports on the number and severity of drug / drug interaction alerts triggered in OnCallData<sup>TM</sup> during each month of the study.

It would stand to reason that e-prescribing's impact on adverse drug events would be directly related to the type of clinical decision support offered by the e-prescribing application. However, a more carefully controlled study, with access to patient charts, is necessary to fully and accurately understand the impact of e-prescribing on adverse drug events.

#### Cost Benefit of Formulary and Generics

While the data presented above show a significant difference in average prescription costs between e-prescribing and non-e-prescribing physicians, the difference existed in 2004 before

the majority of UHMP physicians began e-prescribing. The cost differences observed are more likely due to differences in patient illness severity and health plan payer, which were not controlled for, either because it was not possible from the data, or time did not permit. A more controlled study is needed to accurately assess the impact of e-prescribing on the average cost of prescriptions. The study would need to compare physicians who wrote the vast majority, if not all, of their prescriptions electronically to those that wrote all prescriptions by hand. The study would need to compare patients with similar illness severity and from similar health plans. Data for such a study would need to capture a unique patient identifier and ICD-9 codes to determine the diagnoses for which the prescriptions were written.

While the data show that e-prescribing physicians generally have lower rates of DUR alerts per 1,000 prescription claims, additional study is needed to fully assess the impact of e-prescribing on this aspect of patient safety.